THE BIOTECHNOLOGY SCIENCE COORDINATION ACT OF 1986

HEARINGS

BEFORE THE

SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT

AND THE

SUBCOMMITTEE ON
SCIENCE, RESEARCH AND TECHNOLOGY

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

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[*] Ranking Republican Member.

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THE BIOTECHNOLOGY SCIENCE COORDINATION ACT OF 1986

WEDNESDAY, JUNE 4, 1986

HOUSE OF REPRESENTATIVES, COMMITTEE ON SCIENCE AND TECHNOLOGY, SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT, AND SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY,
Washington, DC.

The subcommittees met, pursuant to notice, at 2:17 p.m., in room 2325, Rayburn House Office Building, Hon. James Scheuer (chairman of the Subcommittee on Natural Resources, Agriculture Research and Environment) presiding.

Mr. SCHEUER. The two subcommittees will come to order.

We're holding today the first of 2 days of hearings on H.R. 4452, the Biotechnology Science Coordination Act of 1986.

Don, we just got a bell. Do you want to testify and then we'll leave, and I'll withhold my statement until after you finish?

Mr. FUQUA. Oh, that would be fine, Mr. Chairman.

Mr. SCHEUER. All right. This is the first of 2 days of hearings on the Biotechnology Science Coordination Act of 1986 introduced by our first witness, the distinguished chairman, Don Fuqua, chairman of the full Science and Technology Committee.

I'm going to—the hearings are being conducted jointly by the Natural Resources, Agriculture Research and Environment Committee, which I have the honor of chairing, and the Subcommittee on Science Research and Technology, chaired by the Honorable Doug Walgren—yes—who couldn't be with us today.

I will defer some brief opening remarks I have and introduce the chairman of the full committee and the sponsor of this bill, Congressman Don Fuqua.

STATEMENT OF HON. DON FUQUA, A MEMBER OF CONGRESS FROM THE STATE OF FLORIDA

Mr. FUQUA. Thank you, Mr. Chairman, and I appreciate the opportunity, and of course all of you here today know of the long involvement in the biotechnology issues, and many of you have been principal players in that. There's no need to chronicle the history.

But I would like to mention that this has been a long and studied process which has helped to distinguish the current environment which seems to dictate the need for legislation from the previous environment which I believe legislation would have been both premature and inhibiting.

The most recent committee hearings of the three held this year by our Investigations and Oversight Subcommittee have underscored the present need.

The legislative framework outlined in the bill is designed to protect the public safety as well as to guide the industry in its development of biotechnology products and processes. The legislation, as distinct from guidelines, can make the regulatory process more emphatic and clear-cut without being rigid, and this is the primary intent of the bill

Like many new legislative initiatives, the bill is intended to focus the thinking of the concerned community on a set of problems by suggesting a possible solution. This series of hearings will be another step in that evolutionary process. I'm particularly pleased with the comprehensive presentation of the witnesses that are being called to present their views on the bill over the next day and a half.

Each individual will provide a part of the total perspective that you're seeking, and I believe that the approach will help maintain that critical balance between encouraging new and exciting possibilities of biotechnology while carrying out our responsibility to proceed with care and caution.

Let me briefly outline the major provisions of the legislation. First, it establishes a forum under the Office of Science and Technology Policy to address the scientific problems in assessing and making the risks associated with the biotechnology. And, second, it establishes the Biotechnology and Science Research Program to promote cooperation—or cooperative research by the Government and the biotechnology industry. And, third, the bill establishes a clear-cut and uniform process by which we'll be able to assess the risk of those products of biotechnology that will be released into the general environment. I want to spend just a few moments elaborating on each of these components.

The bill creates a statutory Biotechnology Science Coordinating Committee under OSTP to help promote the development of uniform and comprehensive review procedures in the diverse agencies that will regulate the release and use of genetically engineered products.

It seems to me that this coordinating committee could also serve as a focal point for scientists to direct comments and recommendations that apply to the decisions and deliberations made by the Government on the biotechnology issue.

The bill's second directive, the intention—the initiation of a cooperative research program by the Government and by the biotechnology industry is an important step toward avoiding controversy between Government and industry about the quality of basic research and the resulting data. This research program is modeled after the automobile industry's Health Effects Institute with the intent to develop a sound research base for regulatory decisionmaking. This task will no doubt be more difficult in the biotechnology industry, but there is a critical need here to develop the scientific base for risk assessment.

The Biotechnology Science Research Program will be dedicated to the promotion of quality scientific research conducted under the supervision of a board of governors that is independent of both government and industry. We anticipate that this research program will join the research interest and research dollars of both public and private sectors under independent supervision and peer review.

And the third and last directive of the bill provides a framework for the regulation of the products of biotechnology related to the general environment. In establishing this framework, we amend the Toxic Substance Control Act that allows us to address the unique hazard posed by organisms which can reproduce and proliferate. Chemicals often infiltrate the environment through various and unintended vehicles of dissemination, but they do not multiply. In biotechnology we're dealing with a characteristic beyond the capacity of chemicals.

The bill does not affect the existing authority of the Food the Drug Administration and its regulation of biotechnology of products because our focus in this framework is on the genetically-engineered organisms released into the general environment.

In addition, the FDA already administers a permit system that is clear and well understood throughout the industry. The legislation strengthens already existing bodies in both the EPA and the Department of Agriculture to serve as a review mechanism for assessing risk and issue permits for both field testing and eventual commercial use of biotechnology products.

There would actually be three separate levels of permission. The first and most limited would allow a review product to be tested within a small and limited environment. This would be the step beyond the laboratory, but in a real and clearly-confined environment. The data and information accumulated from this level of testing would be examined, analyzed to secure permission to proceed to the second level, which will be a broader scale of field testing, and a similar review and analysis would take place at this level. From the data collected through this expanded permit, then a third permit would be issued which would allow the product to be offered commercially.

These three separate levels of permission would serve as a regulatory mechanism at both EPA and USDA, and let me emphasize the importance of data collection in and of itself. It's from this data we'll be able to make increasingly accurate judgments about the interreaction of genetically-engineered organisms in the environment. Thus, even if an applicant does not move to the next permit level, the data already collected will still be submitted to the appropriate agency.

This legislation has three purposes. First, it would instill confidence in the biotechnology industry that there is a reasonable and reliable mechanism to bridge the territory between laboratory success and chemical venture.

Second, it will facilitate the continuous collection of a body of scientific knowledge about the complex interreaction of genetically-engineered organisms in the environment, and this is a consistent accrual of new information that will aid us in future evaluations and risk assessment.

And, third, it is hoped that this visible and public process—and I have to underline that, Mr. Chairman—of testing biotechnology products will instill the confidence in the general public that the testing is controlled and safe and that the eventual commercial products can be safely used. In addition, this framework might well serve as a model for other nations.

The field of biotechnology perhaps best exemplifies the accelerated pace of science and technology in today's society—the transition from basic science of technology development to a product that is occurring more and more rapidly and will continue to escalate in the future, and this makes the competition in the global community of industrial nations more intense and the pre-eminence of any nation more precarious.

America has been the world's leader in biotechnology research. We've had the opportunity and the capacity to continue this preeminence and to be the world's foremost competitor of biotechnology products and processes in the international marketplace, and we all share the same goal. However, the only way to achieve this is to communicate and cooperate. Cooperation does not mean that there should be no dissenters or disagreements, but rather that all concerned share the responsibility for reasonable solutions. And if we polarize our efforts or work at cross purposes, we've relinquished our international lead.

And biotechnology has the potential to solve some of the world's most basic problems, those of hunger and disease. We're all here today to hasten the process of those solutions.

And I look forward to the comments and contributions of all of these distinguished witnesses.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Fuqua follows:]

TESTIMONY BY
HON. DON FUQUA
AT JOINT HEARINGS OF THE
SCIENCE RESEARCH AND TECHNOLOGY SUBCOMMITTEE
AND THE
NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT SUBCOMMITTEE

on
H.R. 4452
The Biotechnology Science Coordination Act of 1986
June 4, 1986

I am pleased to have the opportunity to appear as a witness at the opening of these joint hearings on H.R. 4452.

All of you here today know the Science and Technology Committee's long involvement in biotechnology issues. In fact many of you have been principal players in that involvement over the years.

There is no need to chronicle that history today. However, I would like to mention that it is that long and studied process that has helped to distinguish the current environment which seems to dictate a need for legislation from the previous environment when I believe that legislation would have been both premature and inhibiting. The most recent Committee hearings, the three held this year by our Investigations and Oversight Subcommittee, have underscored the present need.

The legislative framework outlined by H.R. 4452 is designed to protect the public's safety as well as to guide the industry in its development of biotechnology products and processes. Legislation, as distinct from guidelines, can make the regulatory process more emphatic and clear-cut without being rigid. This is the primary intent of the Biotechnology Science Coordination Act of 1986.

Like many new legislative initiatives, this bill is intended to focus the thinking of the concerned community on a set of problems by suggesting a possible solution.

This series of hearings will be another step in the evolution of that process. I am particularly pleased with the comprehensive representation of witnesses being called to present their views on the bill over the next day and one half.

Each individual will provide a part of the total perspective that you seek. I believe that this approach will help maintain that critical balance between encouraging the new and exciting possibilities of biotechnology while carrying out our responsibility to proceed with care and caution.

Let me briefly outline the major provisions of the legislation.

First, it establishes a forum under the Office of Science and Technology Policy to address the scientific problems in assessing and managing the risks associated with biotechnology.

Second, it establishes a Biotechnology Science Research Program to promote cooperative research by the government and the biotechnology industry.

And third, the bill establishes a clear-cut and uniform process by which we will be able to assess the risks of those products of biotechnology that will be released into the general environment.

I want to spend a moment elaborating on each of these components. Let me begin with the forum.

The bill creates a statutory Biotechnology Science Coordinating Committee under OSTP to help promote the development of uniform and comprehensive review procedures in the diverse agencies that will regulate the release and use of genetically engineered products.

It seems to me that this Coordinating Committee could also serve as a focal point for scientists to direct comments and recommendations that apply to the decisions and deliberations made by the government on biotechnology issues.

The bill's second directive, the initiation of a cooperative research program by the government and the biotechnology industry is an important step toward avoiding controversy between government and industry about the quality of basic research and the resulting data.

This research program is modeled after the automobile industry's Health Effects Institute, with the intent to develop a sound research base for regulatory decision-making. This task will no doubt be more difficult in the biotechnology industry, but there is a critical need here to develop the scientific base for risk assessment.

The Biotechnology Science Research Program will be dedicated to the promotion of quality scientific research conducted under the supervision of a Board of Governors that is independent of both government and industry. We anticipate that this research program will join the research interests and research dollars of both the public and private sectors under independent supervision and peer review.

The third and last directive of the bill provides a framework for the regulation of the products of biotechnology released into the general environment. In establishing this framework, we amended the Toxic Substances Control Act (TSCA) to allow us to address the unique hazards posed by organisms which can reproduce and proliferate. Chemicals often infiltrate the environment through various and unintended vehicles of dissemination but they do not multiply. In biotechnology, we are dealing with a characteristic beyond the capacity of chemicals.

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The legislation strengthens already existing bodies in both the Environmental Protection Agency and the Department of Agriculture to serve as the review mechanisms for assessing risks and issuing permits for both field testing and eventual commercial use of biotechnology products.

There would actually be three separate levels of permission. The first and most limited would allow a reviewed product to be tested within a small and limited environment. This would be the step beyond the laboratory -- in a real but clearly confined environment.

Data and information accumulated from this level of testing would be examined and analyzed to secure permission to proceed to the second level which would be a broader scale of field testing. A similar review and analysis would take place at this level. From the data collected through this expanded permit, the third permit would be issued which would allow the product to be offered commercially. These three separate levels of permission would serve as the regulatory mechanism at both EPA and USDA.

Let me emphasize the importance of the data collection in and of itself. It is from this data that we will be able to make increasingly accurate judgments about the interaction of genetically engineered organisms in the environment. Thus, even if an applicant does not move to the next permit level, the data already collected will still be submitted to the appropriate agency.

This legislation has three purposes. First, it should instill confidence in the biotechnology industry that there is a reasonable and reliable mechanism to bridge the territory between a laboratory success and a commercial venture.

Second, it will facilitate the continuous collection of a body of scientific knowledge about the complex interactions of genetically engineered organisms in the environment. This consistent accrual of new information will aid us in future evaluations and risk assessment.

Third, it is hoped that this visible and public process of testing biotechnology products will instill confidence in the general public that the testing is controlled and safe and that the eventual commercial products can be safely used. In addition, this framework might well serve as a model for other nations to emulate.

The field of biotechnology perhaps best exemplifies the accelerated pace of science and technology in today's society. The transition from basic science to technology development to product is occurring more and more rapidly, and will continue to escalate in the future. This makes competition in the global community of industrial nations more intense, and the preeminence of any one nation more precarious.

America has been the world's leader in biotechnology research. We have the opportunity and the capability to continue this prominence, and to be the world's foremost competitor for biotechnology products and processes in the international marketplace. We all share the same goal. However, the only way to achieve it is to communicate and cooperate. Cooperation does not mean that there should be no dissenters or disagreements, but rather that all concerned share the responsibility for reasonable resolutions. If we polarize our efforts or work at cross-purposes, we will relinquish our international lead.

Biotechnology has the potential to solve some of the world's most basic problems -- those of hunger and disease. We are all here today to hasten the progress of those solutions. I look forward to the comments and contributions of all the distinguished witnesses.

Thank you.

Mr. SCHEUER. I congratulate the chairman on his leadership in bringing this bill to the point where it is now.

And at this time we barely have time to make this vote, so we'll suspend for about 12 or 13 minutes.

[Recess taken.]

Mr. SCHEUER. The subcommittee will resume.

We are going to have several questions for our chairman, Don Fuqua, and then we may have some statements for the record.

Mr. Chairman—first question—do all of the Federal agencies involved here have a clear and sufficient authority to review all genetically-engineered organisms intended for environmental release in both research and commercial settings? In other words, is it just a question of issuing guidelines to guide the agencies or is legislation needed to give them the authority to make all of these——

Mr. FUQUA. Mr. Chairman, I would think that there probably exists—and you ask a point that probably counsel could more specifically answer—it is my understanding——

The REPORTER. Mr. Fuqua, just a moment.

I don't think the system is on, Mr. Scheuer.

Mr. SCHEUER. Pardon?

The REPORTER. I don't think the system is on. I'm not receiving anything.

Mr. SCHEUER. The mike isn't on?

[Pause to fix microphones.]

Mr. SCHEUER. Shall I read the question?

The REPORTER. Yes; would you? Thank you.

Mr. SCHEUER. Mr. Chairman, in your opinion, do the various Federal agencies involved in biogenetic engineering—do they have clear and sufficient authority to review all the genetically-engineered organisms intended for environmental release in both research and in commercial settings?

Mr. FUQUA. I would think that they had the authority. What we're attempting to do in this legislation is using that authority that they currently have in order to coordinate the use of biotechnology that applications will be made to that agency. I don't think we're really extending any authority that they do not currently have or is not currently on law.

Mr. SCHEUER. Do you think it would help the biotechnology industry to have a clear and coherent set of official definitions and regulations under which to operate? Do delays in the promulgation of such official regulations and definitions hamper the industry and cripple its efforts?

Mr. FUQUA. Well, I think it does. Without something to coordinate for a uniform system of rules and regulations and guidelines—I would prefer to refer to it—then you may have USDA with one set of rules or requirements; you may have EPA with another set. I think it would be much better if they were coordinated and uniform so that the industry would understand them, and, furthermore, that the public would understand that—that there would be—if one happened to be more stringent than the other, then somebody may be inclined to go to the less stringent. This is intended to have uniform guidelines, so that if you went to USDA, you are going by the same rules if you had gone to EPA. And I think it would be much better, and, furthermore, I think the public would have much greater confidence in what we're attempting to do if there was some type of uniform guidelines.

Mr. **Scheuer**. In assessing the risks of environmental damage and injury, is it appropriate for these agencies to balance and assess both the benefits and the risks of a product in determining whether to permit its release in the environment?

Mr. **Fuqua**. That's what we're intending to do. There has to be a certain amount of risk assessment, as I mentioned in my statement, and there can be certain types of good that may come. Suppose that we find what we think is a potential cure for cancer or development of some drug that could be used for that, or other heart disease or other genetically-inherited diseases that we have that are known—that we must look at the risk.

For instance, a good case in point is the saccharin issue, and I'm not trying to compare that with this, but it was determined that as long as people were forewarned that intake of saccharin, depending on whether they were diabetic or whether they were trying to lose weight, or other types of side effects that they might have, that the amounts that were given off, even though it was carcinogenic, that it was a risk that may be worth taking and that individual under supervision would have to make that choice themselves.

We make risk assessment every day, whether we fly in an airplane or we cross a street or we drive an automobile. That's all part of risk assessment. I think we have to look at where the benefits may come from in this, and there may be much more pluses than minuses in trying to evaluate whether this type of genetically-engineered material should be released.

Mr. **Scheuer**. Thank you very much.

Congresswoman Jan Meyers of Kansas.

Mrs. **Meyers**. I have no questions, Mr. Chairman, at this time.

Mr. **Scheuer**. All right.

Congressman Harold Volkmer of Missouri.

Mr. **Volkmer**. I just want to commend the chairman for the legislation and giving us an initial framework in which to work to try to bring about some semblance of organization, as the gentleman—uniformity within the regulatory process, and I wish to commend the gentleman for the legislation.

Mr. **Fuqua**. Thank you.

Mr. **Scheuer**. Thank you.

Congressman Don Ritter of Pennsylvania.

Mr. **Ritter**. Thank you, Mr. Chairman.

I have no comments. I look forward to listening to the witnesses.

Mr. **Scheuer**. All right. Thank you very, very much.

Mr. **Fuqua**. Mr. Chairman, just one postscript—and I think one of the most important things, and I mention this in my formal remarks, but I can't emphasize this any more—or any greater—of how strong I feel that it's important that there be public confidence in what we're doing. If we do not, then I think we have the potential of destroying something that could be a great means of solving two of the great problems we have in this country, and that is hunger and disease. They are great problems. I know the chairman has been greatly interested in those. Our committee has worked in that area.

If the public is not convinced that their interests are being taken care of, then we could destroy at its infancy something that has a potential to be a great thing for humanity.

Mr. Scheuer. Thank you very, very much, Mr. Chairman.

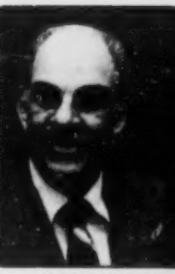
Mr. Fuqua. Thank you.

Mr. Scheuer. We again all congratulate on your leadership in bringing this legislation to us.

Right now we'll call the first group of witnesses: Dr. Dick Johnson, Assistant Director of the Office of Science and Technology Policy; accompanied by Dr. David Kingsbury, chairman of the Biotechnology Science Coordinating Council and Associate Director of the Biological, Behavioral and Social Sciences of the National Science Foundation.

All right. I will ask unanimous consent for my opening remarks to be placed in the printed record at the very beginning of this hearing, before Congressman Fuqua's testimony.

[The prepared statement of Mr. Scheuer follows:]



Congressman
James H.
Scheuer

FOR IMMEDIATE RELEASE:
June 4, 1986

FURTHER INFORMATION:
Mike Rodemeyer -- 226-6980
George Burke -- 225-5471

STATEMENT OF HON. JAMES H. SCHEUER, CHAIRMAN

Subcommittee on Natural Resources, Agriculture Research and Environment

Today, we are holding the first of two days of hearings on H.R. 4452, the "Biotechnology Science Coordination Act of 1986", introduced by the Chairman of the full Science and Technology Committee, the distinguished Honorable Don Fuqua.

These hearings are being conducted jointly by the Subcommittee on Natural Resources, Agriculture Research and Environment, which I chair, and the Subcommittee on Science, Research and Technology, chaired by the Honorable Doug Walgren.

Today's hearings are the first to consider legislation specifically concerned with the potential risks of releasing genetically-engineered organisms into the environment.

Biotechnology surely promises new products which will substantially benefit mankind: new drugs that offer hope against heart disease, cancer, and genetic disorders; non-chemical pesticides which can target pests precisely, with no residual effects; plants which are resistant to disease, drought, and pests.

But in this age of Bhophal, Chernobyl, and Love Canal, it comes only too naturally to be suspicious of the bright promises of new technologies. Indeed, concerns have been raised about the risks to the public health and the environment of releasing novel life forms -- created by scientists, not nature -- into the environment. Unlike chemicals, organisms can reproduce and grow far beyond their original area of use, interacting with other organisms in the environment in ways that are difficult to predict. Critics point to examples of natural invasions -- like starlings, chestnut tree blight, kudzu, and the like -- to illustrate the possible risks.

While most scientists believe that such risks are low, there appears to be agreement that assessing the risks is difficult, due in part to the general lack of scientific knowledge about microbial activity in the environment. The Administration has been grappling with this issue for several years, and we will have an opportunity to hear from Administration witnesses at these hearings.

The Science and Technology Committee has also been deeply involved with the development of biotechnology since the 1970's. More recently, particularly in hearings before the Investigations and Oversight Subcommittee, the issues surrounding deliberate release of genetically-engineered organisms have been explored.

The bill, H R. 4452, addresses the issue by establishing a coordinated federal biotechnology policy, one that would promote the science that can help improve risk assessment while moving cautiously forward, based on data obtained from small-scale field testing.

It seems to me that this bill reflects an appropriately cautious approach. All too often, we rush to embrace new technologies, only to reap unintended and unforeseen damage to the environment years later. In this bill, Congress has a rare opportunity to make sure that we learn from foresight, not hindsight.

Nevertheless, the issue of regulating environmental releases of biotechnology products is a complex one, and one that presents a wealth of new policy concerns that will be weighed carefully by this Committee and the Congress. Our hope in this set of hearings is to explore fully and diligently, not only the specific proposal set out in the bill, but also the range of options that Congress has before it.

# # #

Mr. **Scheuer**. I now recognize Congresswoman Claudine Schneider of Rhode Island for her opening statement.

Miss **Schneider**. Well, Mr. Chairman, I just wanted to commend you for calling these joint hearings, and I think that there's very little question that we have the opportunity to pursue some questions that are right now at the forefront of this whole field. And it seems to me that we have the opportunity to develop new products and to establish new markets and improve our industrial competitiveness.

As a matter of fact, as a member of the steering committee for the Business Higher Education Forum, which is made up of the Fortune 500 companies and the presidents of major universities, I've had the opportunity to discuss this legislation and some of the provisions of it, and there seems to be a great deal of interest on the part of many of these companies and universities.

There's no question that in terms of our international competitiveness we keep focusing on Japan, and we have to note that Japan has actually targeted biotechnology as a key industry of their future. So, needless to say, we know that our pursuits have the potential of being of great benefit to mankind, whether we're talking about agricultural production or eliminating various diseases, or even eliminating some hazardous wastes that continue to pollute our groundwater or other parts of our environment.

And the opportunities for us to cause great harm also exist in our pursuit of biotechnology. So I think that the regulatory system that we have in place that is being discussed will prevent the introduction of harmful biotech products and also has the potential of providing industry with a clear and certain message as to what the intents of Government are, and also, third, to build and maintain public confidence. And I think that the proposal for public hearings and public participation is of utmost importance because we are on the edge of a new and emerging era, and one that I feel is very exciting. So we must tread cautiously, but yet we still must continue to move ahead.

Thank you, Mr. Chairman.

Mr. **Scheuer**. OK. Congressman Volkmer, do you have a statement?

Mr. **Volkmer**. No; I'll have mine tomorrow.

Mr. **Scheuer**. All right. Then Congresswoman Jan Meyers.

Mrs. **Meyers**. No comments at this time.

Mr. **Scheuer**. Congressman Don Ritter, statement?

Mr. **Ritter**. No comments, Mr. Chairman.

Mr. **Scheuer**. OK. All right, then, we'll hear from you, Dr. Johnson. Your statement will be printed in full at this point in the record, so why don't you take 6 or 7 minutes and chat with us informally, giving us the highlights of your testimony, and then we'll have some questions for you?

STATEMENT OF DR. DICK JOHNSON, ASSISTANT DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY POLICY, ACCOMPANIED BY DR. DAVID KINGSBURY, CHAIRMAN BIOTECHNOLOGY SCIENCE COORDINATING COUNCIL AND ASSISTANT DIRECTOR, BIOLOGICAL, BEHAVIORAL AND SOCIAL SCIENCES, NATIONAL SCIENCE FOUNDATION, AND ROBERT RABIN, ASSISTANT DIRECTOR FOR LIFE SCIENCES, OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Dr. **Johnson**. OK. Thank you, Mr. Chairman.

With your permission, I would also like to have Dr. Rabin answer questions or assist in the testimony this afternoon.

Mr. **Scheuer**. Well, first of all, going off the record, you might make sure your mike is on——

Dr. **Johnson**. Oh, I'm sorry.

Mr. **Scheuer** [continuing]. Because I'm having trouble hearing you.

OK, pull it a little closer. Pull it closer.

Do you want to introduce for the record Dr. Rabin and Dr. Kingsbury?

Dr. **Johnson**. Yes.

Mr. **Scheuer**. Identify them?

Dr. **Johnson**. I'd like to introduce Dr. Robert Rabin who is the Assistant Director for Life Sciences in the Office of Science and Technology Policy. Dr. Rabin is on my right.

And Dr. David Kingsbury who is at the National Science Foundation and Assistant Director for Biological, Behavioral and Social Sciences.

I appreciate——

Mr. **Scheuer**. I want to suggest again that you pull your mike a little closer to you. I think people will hear a little bit better.

Dr. **Johnson**. Fine.

Mr. **Scheuer**. OK?

Dr. **Johnson**. Sure.

I appreciate the invitation to meet with you to discuss OSTP's roles and activities relating to biotechnology.

Biotechnology includes the use of various genetic manipulation techniques that have been or will be involved in the manufacture of many different types of products. Federal agencies regulate these products according to their use. Such an approach to regulation has enabled our regulatory agencies to develop years of experience in regulatory practice for biotechnology product areas, including drugs, foods, pesticides, and plant and animal products.

Accordingly, reliance on the existing product-by-product approach provides strong and immediate assurance to the public that health and the environment are appropriately protected.

In those areas where new biotechnology products appear to pose increased risk the regulatory framework provides additional requirements to insure their safety.

Some remarks on the past and current involvement of the Office of Science and Technology policy in this area and the role of the Domestic Policy Council working group on biotechnology will, I believe, serve as a useful introduction to these hearings.

In April 1984 the former cabinet council on natural resources and the environment established a working group on biotechnology chaired by the Director of OSTP. The council structure has since been modified and the working group on biotechnology now reports to the Domestic Policy Council. The Director of OSTP chairs the working group, but Dr. Kingsbury, the Assistant Director at NSF that I just introduced, directs the day-to-day business of that working group.

Staff support for the working group is provided by OSTP, and the DPC working group has 18 members representing different Federal agencies and offices of the Executive Office of the President.

Its primary responsibility is to coordinate interagency review of the broad spectrum of issues that relate to domestic and international commercialization of biotechnology, including, among others, regulatory, jurisdictional, commercial, patent, and research and development.

The first task of the working group was to review the adequacy of existing statutes and regulations to insure the protection of public health and the environment, and the development of new technologies and socially useful products.

On December 31, 1984, OSTP published for public comment in the Federal Register the results of the first phase of the working group's efforts, a proposed regulatory framework including policy statements from EPA, USDA, and FDA and a description of an advisory mechanism. On April 12, 1985, OSHA published its policy statement, thus completing the proposed framework.

In light of the comments received——

Mr. SCHEUER. Excuse me?

Dr. JOHNSON. Yes.

Mr. SCHEUER. Those policy statements and the regulatory framework that you've mentioned were published several years ago. I think what we asked you in our letter was to give us your present policy as it has developed and your present regulatory framework as it has developed, and I hope you'll be able to do that in your testimony.

Mr. JOHNSON. Yes, right. I have only a very brief statement addressing some of the present status and also I've asked Dr. Kingsbury to make some statements with regard to those specific activities in the OSTP committee and in the working group for the Domestic Policy Council.

Mr. SCHEUER. Well, who can tell us what the policy formulation has been up until now? What public policies have you developed up to now for the benefit of the Congress and the industry and the public, and what regulatory framework have you developed up to now that you can tell us about today for the benefit of the Congress, the industry, and the public?

Dr. JOHNSON. Yes.

Mr. SCHEUER. Now those are very specific questions, and we would like you to give us very specific answers.

Dr. JOHNSON. Yes, we will address those——

Mr. SCHEUER. Good.

Dr. JOHNSON [continuing]. Between myself and Dr. Kingsbury.

Mr. SCHEUER. Good.

Dr. Johnson. As I was indicating, in light of the comments that were received, the working group has reconsidered these proposals and prepared revised documents. The revised documents—the revised policy statements from OSHA, EPA, USDA, FDA, and NIH are now in the final Domestic Policy Council approval process. I shall be pleased to provide members of the subcommittee with copies as soon as they are available.

Mr. Scheuer. When is that likely to be?

Dr. Johnson. Well, my understanding is that that will be within a few days.

Dr. Kingsbury, do you want to comment on that?

Dr. Kingsbury. Well, we don't know exactly to the day which day the documents will be released. They're currently in the internal final stages of approval, and we anticipate that they will be available to the Federal Register sometime next week. At the time they go to the Federal Register of course they become public documents.

Mr. Volkmer. Mr. Chairman, will you yield on that?

Mr. Scheuer. I don't quite understand this. We want your testimony on the bill based on the policy that you have developed and on the regs that you have developed. Now if all that is going to be available to deliver to Members of Congress 48 hours from now, why can't you give us what you've done? I mean, it must be at the printer's by now. Why can't you give us specific information on your policy development and your development of administrative regs and tell us how those impinge on our bill?

Dr. Johnson. Yes, Mr. Chairman, let me just indicate that it is not at the printer's yet. It's in the final approval process within the Domestic Policy Council.

Mr. Scheuer. Well, did we schedule this hearing a couple of days too early for your convenience and for your process?

Dr. Johnson. Well, in—very certainly it would have been much more valuable to have occurred after the release of that particular set of data.

Mr. Scheuer. See, we cancelled the hearing 2 weeks ago so that you could be up to speed. Now you're telling us that we're 2 days too early. We were 2 weeks too early 2 weeks ago. I don't think that's being responsive to a congressional request for information and for policy guidance.

Dr. Johnson. Well, Mr. Chairman, I——

Mr. Scheuer. Now do we have to schedule another hearing to get responsive answers from you?

Dr. Johnson. Well, Mr. Chairman, I believe we did try to respond to your questions, and perhaps it would be useful to proceed with the testimony to bring out those particular responses.

For example, there are elements of the bill regarding the functions of OSTP and the way in which you would address, say, the funding of some of the biomedic—biotechnology research. And I did intend to address those as part of your questions.

Mr. Volkmer. Mr. Chairman.

Mr. Scheuer. Yes, excuse me.

In looking at your testimony, there may be something that I'm missing, but I see on page 4 you sum up your testimony by saying that, "These statutes provide sufficient authority, direction, and flexibility for protection of the public health and the environment."

Is there anything else in your testimony that I should know?

Dr. JOHNSON. Yes, sir, I believe I would like to comment on your proposed regulations with regard to OSTP functions in the area of biotechnology, specifically the proposed assignment of additional responsibilities within OSTP.

Mr. SCHEUER. This is really puzzling to us. We'd like to know what policy you have developed and we'd like to know what regs you have developed. Would you prefer to suspend this hearing as far as you're concerned and we'll schedule another date in a week or two?

Dr. JOHNSON. Well, I would say, yes, that would——

Mr. SCHEUER. So that you could give us some responsive answers? There's no point in wasting a lot of time.

Dr. JOHNSON. OK, I believe with regard to that particular part of your bill, yes, I think that would be useful to address those specific issues.

Dr. Kingsbury, who's chairman of the working group——

Dr. KINGSBURY. If I may—the testimony that we wrote was written in the context of the fact that we're in the final approval stage of the Federal Register notice that comes out with the specific wording of the final policy statement. I would be delighted to discuss with you the framework in which that statement was put together, the philosophy behind it.

If you will allow us to do the philosophical background, we can talk about the statutes that are involved without giving you the precise wording, which has not yet been fully approved by the Domestic Policy Council.

Mr. SCHEUER. How soon will it be specific——

Dr. KINGSBURY. Unfortunately, to I think the frustration of all of us, we are not members of the Domestic Policy Council and we don't know what that process is. This is the first time that one of our notices has gone through the entire DPC review process. Our last notice, the first part of this notice, which was the November 14 notice, which is part 1 of the final statement, went through a truncated process of approval. This one is a much broader statement. It requires much more approval, and it's really out of our hands. And so we're as frustrated as you are in terms of expecting its release. We had anticipated its release prior to this hearing.

I was one of the people who had requested that the first—that Mr. Volkmer's hearing be delayed because we really honestly felt that we would be able to come here. The process is taking a little bit more time because a number of other problems have intervened in the process of the Domestic Policy Council. It's a very busy group of people. And I know that they're working very hard on this. We have tried to assist in that. It's taking a little bit longer than we had anticipated.

Mr. SCHEUER. What's your time estimate as to when——

Dr. KINGSBURY. I really hope that it's out by next week. I mean, I'm as frustrated as you are, honestly.

Mr. SCHEUER. I might say I get the feeling that I'm trying to punch my way out of a bag of wet kleenex. [Laughter.]

Dr. **Kingsbury**. I would be happy to go ahead and go through the general framework with you. I don't have any problems with that. I don't think that would be a violation of any of the approval process, but the specific wording I think we would have some problems with.

Mr. **Scheuer**. I'm going to recognize Congressman Harold Volkmer at this time.

Mr. **Volkmer**. Thank you, Mr. Chairman.

Because I'm one of those who is quite concerned that there has not been action, as I understand it, by the White House. As I understand—you correct me if I'm wrong—that the Domestic Policy Council has already signed off on the preamble and the guidelines and that it's now sitting up there somewhere in the White House for approval. Am I right or wrong?

Dr. **Kingsbury**. It's my——

Mr. **Volkmer**. May 20, to give you a date. [Laughter.]

Dr. **Kingsbury**. You're trying to paint me into a corner, sir. [Laughter.]

Mr. **Volkmer**. Yes, because I'm going to come out with another one in a minute and then another real bombshell right after that.

Dr. **Kingsbury**. Well, I'm ready.

Dr. **Johnson**. Well, I could address that, I think, from the point of view of the organization. Indeed, it is very far along in the Domestic Policy Council. It's right down to sort of the very final review and decisionmaking on its release without getting into individual responsibilities there.

Dr. **Kingsbury**. The date of May 20—you have correct—was the date of presentation to the assembled Domestic Policy Council with its staff. That was the beginning of the eventual process, as Dr. Johnson says. It is now in the final stages of that process.

Mr. **Volkmer**. All right. Now the problem I have a little bit as a Member of Congress is to read a newspaper account on May 30, publishing excerpts from the guidelines.

Dr. **Kingsbury**. Where was that?

Mr. **Volkmer**. That was in the "Inside EPA" on May 30, 1986. Then I'm going to give you one more. Now this is a real bombshell.

Dr. **Kingsbury**. That was——

Mr. **Volkmer**. This afternoon we're all going to get to look at your preamble. Someone right here in this room right now has a copy of it. I don't. No Member of Congress that I know of has—no Member of Congress.

Dr. **Kingsbury**. I don't——

Miss **Schneider**. Would the gentleman yield?

Mr. **Volkmer**. Yes.

Miss **Schneider**. I think that this is perhaps counterproductive, what little exercise we're going through now. And since we all have very valuable time, why don't we suspend with these particular witnesses and wait until they do have the specifics when we can ask them specific technical questions?

Mr. Chairman, I would like to move that.

Mr. **Scheuer**. I think we ought to release this panel, and you let us know when you've done your homework and when——

Mr. VOLKMER. Mr. Chairman, before you do that, I have other questions pertaining to the legislation that do not pertain to the guidelines that I would like to ask these witnesses.

Mr. SCHEUER. Fine.

Mr. VOLKMER. I just wanted to show my little displeasure with the administration in formulating those guidelines, which were to be released January 31, 1986, as you well remember.

Now, Dr. Kingsbury, one of the tasks of the BSCC is to identify gaps in scientific knowledge; is that correct?

Dr. KINGSBURY. That's correct.

Mr. VOLKMER. Now do you agree with the statement that there does exist a gap in the area of predictive ecology?

Dr. KINGSBURY. I'm not sure I know what predictive ecology is.

Mr. VOLKMER. All right. Then let's say prediction of the events that will occur following the release of a product that has been changed or genetically engineered through not evolutionary processes, but rapidly through genetic engineering and released into the environment. And can you tell me what's going to happen on every product?

Dr. KINGSBURY. If what you're really asking is, Do we know exactly without any additional testing how a microorganism released into the environment is going to act with great precision, I would have to say that is an area in which there is scientific uncertainty.

One knows within a broad framework of what a particular microorganism may do because we know where the microorganism came from, and we know something about its life cycle before it was genetically manipulated. That gives us some predicting value. It tells you what testing that needs to be done.

To be able to say in an abstract sense, yes, we know what microorganism XYZ will do without having done any empirical data gathering, that's correct, we do not have a modeling system that allows us to do that.

Mr. VOLKMER. We do not—we have data gaps, lack of information?

Dr. KINGSBURY. That's right.

Mr. VOLKMER. Is that correct?

Dr. KINGSBURY. In that sense we have a lack of information; right.

Mr. VOLKMER. Now, as I understand, title II of the bill now before us would establish a joint industry-Government research program to facilitate the development and regulation of biotechnology products under the Office of Science and Technology Policy. In particular, this research program would promote scientific research which would enable regulatory agencies to assess risk of environment release more accurately and more confidently.

Now what are your views concerning such a joint industry-Government research effort?

Dr. KINGSBURY. I think that this is an excellent idea. I have made that comment in public on a number of occasions during the biotechnology-related Brookings meeting in this—several months ago I made that comment. We have been working together with the American Society for Microbiology which is scheduled to appear here next on this notion—whether we should be housed within OSTP I think is a point at which we disagree. The notion behind a private and Government cooperative institute to do this kind of work I think is a sound idea and a very good one, and——

Mr. VOLKMER. In other words——

Dr. KINGSBURY [continuing]. Which I would endorse, that section—

Mr. VOLKMER. Your problem is that to put it within OSTP, not out here maybe by itself?

Dr. KINGSBURY. That's correct.

Mr. VOLKMER. As an independent?

Dr. KINGSBURY. Right. I would use the EPRI model rather than the health effects model.

Mr. VOLKMER. All right.

Dr. JOHNSON. May I add to that?

Mr. VOLKMER. Yes, Dr. Johnson.

Dr. JOHNSON. Just on the—from a management point of view, OSTP is not structured to manage in a line management fashion the kind of research programs that you describe. It is primarily, as now structured, a policy model and not one that can manage, and does not manage, budgets and resources and review of research programs. Thank you.

Mr. VOLKMER. Now I'd like to talk just briefly, if we could, about the BSCC.

Dr. KINGSBURY. Yes, sir.

Mr. VOLKMER. And, as I understand it, we have a seven-member organization that is chaired by yourself and ultimately with the head of the——

Dr. KINGSBURY. The Director of the NIH; yes, sir.

Mr. VOLKMER. NIH; right. And that—how often do you meet?

Dr. KINGSBURY. We've met on an average of once a month since the establishment of the committee. The precise number I do not have at my fingertips right now, but it's been slightly more than one meeting per month.

Mr. VOLKMER. Now how do you rotate the chairmanship, monthly, by meeting, or by year?

Dr. KINGSBURY. No, we have not. We have—the charter calls for an indefined [sic] process of chair rotation, and up to this point I have served as the Chair for the entire process.

Mr. VOLKMER. So you really haven't rotated yet?——

Dr. KINGSBURY. Not yet; that's right. The committee is less than a year old. When Dr. Keyworth signed the charter for the committee he wrote me a letter asking me to serve as his first chairman. The implication was that it would be for a 1-year period.

Mr. VOLKMER. Now the personnel that make it up, as I understand, you are the only microbiologist or biology expert, if I may say so, within the committee?

Dr. KINGSBURY. No, sir. Dr. Frank Young, who is the Commissioner of the FDA, is an eminent microbiologist. He's a pathologist by training, with also microbiological training. He has a distinguished vitae in terms of microbial genetics and has been a well-known figure in that area for quite some time.

Mr. VOLKMER. OK. But, then, he and you, then, are the only two?

Dr. KINGSBURY. I think that it would be fair to say we're the only disciplinary molecular biologists. Of course, Dr. Wyngarden has had a great deal of training in biochemistry and in internal medicine.

Dr. JOHNSON. May I add to that——

Mr. VOLKMER. Yes.

Dr. JOHNSON. Just from the committee's structure point of view, as a committee under the Federal Coordinating Council of Science, Engineering and Technology, that committee can draw on the resources of agencies or outside groups as it is needed.

Mr. VOLKMER. Yes, but I understand at the meetings that only the persons themselves need a designee are those that attend and participate in the discussions; it that not correct?

Dr. KINGSBURY. That's correct. At the meetings—let me—maybe I should try to put this into a slightly different context.

At the meetings we do have a rule that it's principals only, and the reason for that is, as I had in my testimony, was to provide an atmosphere of confidentiality in which the regulators felt free to have open discussions in which all of us could openly ask questions of the regulators, because this is really the kinds of questions that we want to go into.

As you've pointed out, there are potential knowledge gaps. Those are the questions that we need to delve into. The regulators are the people who are groping with a number of questions that come up. They need a—what I would call a confidential environment in which to open up about some of those questions. So we've held it to principals only.

We have put together a subcommittee structure which draws now on a variety of other agencies and a variety of staff people who have a great deal of expertise. It was always our intention to operate the BSCC through a subcommittee structure which called on the agency staffs that had the disciplinary expertise to be able to handle the specific questions that were coming to the BSCC, and that the levels of discussion at the BSCC would be relying on that staff input.

Mr. VOLKMER. Now I assume, then, that as chairman you would be responsible for setting the time of meetings, the agenda for the meetings, et cetera?

Dr. KINGSBURY. That's correct. That's correct.

I should also make another comment that, because of the nature of the regulatory environment, confidential business information is something that we're particularly concerned about. And to not establish an environment in which CBI is totally excluded, of course, would compromise the ability of the committee to function. And so a principals only rule was very helpful in that context.

Mr. VOLKMER. But now the principals only are the ones who develop the guidelines?

Dr. KINGSBURY. No, sir. The guidelines were developed, as was mentioned, by the domestic policy working group, which is represented by a large number of agencies and Executive offices.

The BSCC is really representative of five agencies. The DPC working group is much more broadly representative, with 18 agencies and offices that include State, for example, the Defense Department, DOE, the U.S. Trade Representative's office—a wide variety of activities, so that—and Justice as well—so that we brought a much different context into the development of the policy statement than we have brought to the question of the scientific questions of risk assessment and regulatory oversight.

Mr. VOLKMER. The question I have, then, because undoubtedly I was under the wrong impression—the BSCC, then, did not develop the guidelines initially?

Dr. KINGSBURY. No, sir. The BSCC——

Mr. VOLKMER. Nor the preamble?

Dr. KINGSBURY. No, sir. That was the Domestic Policy Council working group that was responsible for the entire development of the guidelines. The working group deferred certain science questions to the BSCC, and in the preamble, as we—as it—in its final form becomes a public document, you will see that there are areas in the preamble in which we identify certain definitions that are used in the policy statement. Those definitions, since they're scientific questions, were developed by the BSCC and referred, then, back to the working group for final approval.

Mr. SCHEUER. Congressman, the witnesses will be back in the next couple of weeks.

Mr. VOLKMER. Yes, but I would like to ask him a couple more right now.

Mr. SCHEUER. OK.

Mr. VOLKMER. Just a few more.

As I understand your statements earlier, your written statement——

Dr. KINGSBURY. Yes, sir.

Mr. VOLKMER [continuing]. It appeared to me that rather than have the—I just wanted to do this clarification—rather than have the independent Government-industry research group doing the research to fill the information that we need and data on risk assessment, et cetera, and this field, that you are suggesting perhaps that the agencies themselves do the research. That was in the written statement. Did I read it improper or——

Dr. KINGSBURY. Excuse me. Let me clarify what my intention was. What I was concerned about is priority setting within the research agencies, and what I was concerned about is that we superimpose over the various agencies a statutory body which has the power to essentially tax those agencies for a specific research field without being able to put that research into the full context of the agency research policy.

And it seems in my mind that the best way to do science policy and to set research agendas is to set them within the full context of individual agency research programs. As I pointed out in my written statement, the NSF has done this and, as you know, this committee has oversight on that activity and it's been reviewed carefully.

The agency should maintain that priority setting, and that's what I was concerned about. As I mentioned earlier, the concept of a Government-private hybrid to do this kind of research, to set research tools, to establish research tools, to do the environmental assessment, I think is a sound idea. I'm just concerned about a statutory body that can force research programs to be twisted out of their established priorities.

Mr. Volkmer. Well, I don't believe there is any intention within the legislation to do that, nor does anybody I think in the Congress that I know of, or even talked about that.

Basically what I was looking to was additional research through this type of independent thing because, to give you an example, what concerns me is right now USDA has, if I remember right, 87 projects ongoing research into the genetic engineering area for a product. But as I remember, in the GAO study I think it was only three of those were actually involved in research on risk assessment related to that, which means that you've got 84 of them where there's possibly nothing to be done. So that's what concerns me.

Dr. Kingsbury. Yes, sir.

Mr. Volkmer. So the last thing—no, I've already pointed out—the last thing I'd like to know, Dr. Johnson—prior to your testimony here today and your statement, did anyone outside the administration, official administration, review your testimony, have it for review?

Dr. Johnson. Outside the administration, we have a consultant who reviewed the testimony.

Mr. Volkmer. Who is that consultant?

Dr. Johnson. Mr. John Cohrssen.

Mr. Volkmer. And if anyone else had it, they——

Mr. Scheuer. Excuse me. Could you identify Mr. John—Dr. John Cohrssen?

Dr. Johnson. Yes. John Cohrssen is right here with the red tie.

Mr. Scheuer. What is his affiliation?

Dr. Johnson. He is a consultant for OST——

Mr. Scheuer. I mean, if he's sitting here with a red tie, you'd think he was a Senator. [Laughter.]

He is with OSTP?

Dr. Johnson. Yes, he is a consultant to OSTP.

Mr. Scheuer. Very good. I yield back.

Dr. Kingsbury. I should add, if I may, that Mr. Cohrssen has been a consultant with the Council on Environmental Quality and OSTP throughout the generation of this—the 2-year cycle of the generation of the policy statements, has been intimately involved in that as well. So it's not that he was brought from outside to do this. He's been intimately involved in this process.

Mr. Volkmer. Thank you, Mr. Chairman. I have no further questions at this time for the witness.

Mr. Scheuer. OK, very good.

Miss Schneider. Mr. Chairman.

Mr. Scheuer. Yes.

Miss Schneider. Considering we have spent an hour and a half and we are real anxious to have this panel return to us at a later time for specifics, I am going to withhold my questions until they return.

Mr. Scheuer. Very good.

Congresswoman Jan Meyers of——

Mrs. Meyers. I will withhold questions, also.

Mr. Scheuer. Congressman Don Ritter of Pennsylvania.

Mr. Ritter. Likewise, Mr. Chairman.

Mr. Scheuer. Congressman Paul Henry.

Mr. **Henry**. No questions, Mr. Chairman.

Mr. **Scheuer**. All right, then, with respect, gentlemen, we'll excuse you now and hope that you'll come back in another week or two when the administration, broadly considered, has done its homework and is ready to deal responsibly with the kind of questions that you're obviously aware we have to ask.

Dr. **Johnson**. Thank you, Mr. Chairman.

Mr. **Scheuer**. Thank you very much.

[The prepared statements of Dr. Johnson and Dr. Kingsbury follow:]

TESTIMONY

OF

RICHARD G. JOHNSON

ACTING DIRECTOR

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

EXECUTIVE OFFICE OF THE PRESIDENT

AND

ACTING SCIENCE ADVISOR TO THE PRESIDENT

BEFORE THE

SUBCOMMITTEE ON SCIENCE, RESEARCH, AND TECHNOLOGY

AND THE

SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT

OF THE

COMMITTEE ON SCIENCE AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

JUNE 4, 1986

I APPRECIATE THE INVITATION TO MEET WITH YOU TO DISCUSS OSTP'S ROLES AND ACTIVITIES RELATING TO BIOTECHNOLOGY.

BIOTECHNOLOGY INCLUDES THE USE OF VARIOUS GENETIC MANIPULATION TECHNIQUES THAT HAVE BEEN, OR WILL BE, INVOLVED IN THE MANUFACTURE OF MANY DIFFERENT TYPES OF PRODUCTS. FEDERAL AGENCIES REGULATE THESE PRODUCTS ACCORDING TO THEIR USE. SUCH AN APPROACH TO REGULATION HAS ENABLED OUR REGULATORY AGENCIES TO DEVELOP YEARS OF EXPERIENCE IN REGULATORY PRACTICE FOR BIOTECHNOLOGY PRODUCT AREAS INCLUDING DRUGS, FOODS, PESTICIDES, AND PLANT AND ANIMAL PRODUCTS. ACCORDINGLY, RELIANCE ON THE EXISTING PRODUCT-BY-PRODUCT APPROACH PROVIDES STRONG AND IMMEDIATE ASSSURANCE TO THE PUBLIC THAT HEALTH AND THE ENVIRONMENT ARE APPROPRIATELY PROTECTED. IN THOSE AREAS WHERE NEW BIOTECHNOLOGY PRODUCTS APPEAR TO POSE INCREASED RISKS, THE REGULATORY FRAMEWORK PROVIDES ADDITIONAL REQUIREMENTS TO ENSURE THEIR SAFETY.

SOME REMARKS ON THE PAST AND CURRENT INVOLVEMENT OF THE OFFICE OF SCIENCE AND TECHNOLOGY POLICY (OSTP) IN THIS AREA, AND THE ROLE OF THE DOMESTIC POLICY COUNCIL WORKING GROUP ON BIOTECHNOLOGY WILL, I BELIEVE, SERVE AS A USEFUL INTRODUCTION TO THESE HEARINGS.

IN APRIL 1984, THE FORMER CABINET COUNCIL ON NATURAL RESOURCES AND THE ENVIRONMENT ESTABLISHED A WORKING GROUP ON BIOTECHNOLOGY

CHAIRED BY THE DIRECTOR OF OSTP. THE COUNCIL STRUCTURE HAS BEEN MODIFIED, AND THE WORKING GROUP ON BIOTECHNOLOGY NOW REPORTS TO THE DOMESTIC POLICY COUNCIL. THE DIRECTOR OF OSTP CHAIRS THE WORKING GROUP, BUT DR. DAVID KINGSBURY, ASSISTANT DIRECTOR FOR BIOLOGICAL, BEHAVIORAL AND SOCIAL SCIENCES AT THE NATIONAL SCIENCE FOUNDATION, DIRECTS ITS DAY-TO-DAY BUSINESS. STAFF SUPPORT FOR THE WORKING GROUP IS PROVIDED BY OSTP. THE DPC WORKING GROUP HAS 18 MEMBERS REPRESENTING DIFFERENT FEDERAL AGENCIES AND OFFICES OF THE EXECUTIVE OFFICE OF THE PRESIDENT. ITS PRIMARY RESPONSIBILITY IS TO COORDINATE INTERAGENCY REVIEW OF THE BROAD SPECTRUM OF ISSUES THAT RELATE TO DOMESTIC AND INTERNATIONAL COMMERCIALIZATION OF BIOTECHNOLOGY, INCLUDING AMONG OTHERS, REGULATORY, JURISDICTIONAL, COMMERCIAL, PATENT, AND RESEARCH AND DEVELOPMENT ISSUES.

THE FIRST TASK OF THE WORKING GROUP WAS TO REVIEW THE ADEQUACY OF EXISTING STATUTES AND REGULATIONS TO ENSURE THE PROTECTION OF PUBLIC HEALTH AND THE ENVIRONMENT, AND THE DEVELOPMENT OF NEW TECHNOLOGIES AND SOCIALLY USEFUL PRODUCTS. ON DECEMBER 31, 1984, OSTP PUBLISHED FOR PUBLIC COMMENT IN THE FEDERAL REGISTER THE RESULTS OF THE FIRST PHASE OF THE WORKING GROUP'S EFFORTS, A PROPOSED REGULATORY FRAMEWORK INCLUDING POLICY STATEMENTS FROM EPA, USDA, AND FDA AND A DESCRIPTION OF AN ADVISORY MECHANISM. ON APRIL 12, 1985, OSHA PUBLISHED ITS POLICY STATEMENT, THUS COMPLETING THE PROPOSED FRAMEWORK. IN LIGHT OF THE THE COMMENTS RECEIVED, THE WORKING GROUP HAS RECONSIDERED THESE PROPOSALS AND PREPARED REVISED DOCUMENTS.

The revised policy statements from OSHA, EPA, USDA, FDA and NIH are now in the final Domestic Policy Council approval process. I shall be pleased to provide members of the Subcommittees with copies as soon as they are available.

With respect to the advisory mechanism, the DPC Working Group concluded that the proposed Federal advisory committee with nongovernment experts, organizationally superimposed over the agency-based committees was not needed; the regulatory and research agencies had, or were establishing, agency advisory committees that would provide public involvement and nongovernment expertise. What was needed was an interagency mechanism allowing for discussion and refinement of scientific issues to develop common approaches and scientific guidelines in an open and frank manner to facilitate the best scientific bases for agency actions. In the performance of its responsiblities, the committee would identify areas where additional scientific research would be necessary.

As a result of these foregoing considerations, the Biotechnology Science Coordinating Committee or BSCC was established October 31, 1985. It is responsible for coordination and consistency of scientific policy and reviews. As was amply described in the Federal Register Notice of November 14, 1985, the BSCC is a subcommittee of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET). (FCCSET is a statutory

INTERAGENCY COORDINATING COMMITTEE CHAIRED BY THE DIRECTOR OF OSTP WITH A MISSION TO COORDINATE FEDERAL SCIENCE ACTIVITIES.) THUS, THE BSCC CONSISTS OF SEVEN SENIOR POLICY OFFICIALS OF AGENCIES INVOLVED IN THE OVERSIGHT OF BIOTECHNOLOGY RESEARCH AND PRODUCTS. DR. KINGSBURY CHAIRS THE BSCC; OSTP PROVIDES STAFF SUPPORT, WITH MARY GANT AS THE EXECUTIVE SECRETARY. ADDITIONAL LEGISLATION TO GUARANTEE ITS EXISTENCE OR TO SUPPORT ITS ACTIVITIES IS NOT JUSTIFIED.

I AM VERY IMPRESSED BY THE PROGRESS MADE BY THE WORKING GROUP AND BY THE BSCC AND COMMEND ALL OF THE PARTICIPANTS WHO HAVE CONTRIBUTED TO THEIR IMPORTANT ACTIVITIES. BOTH BODIES HAVE WORKED UNDER INTENSE PRESSURE TO ESTABLISH A WELL COORDINATED FEDERAL REGULATORY POLICY IN BIOTECHNOLOGY BASED ON CURRENT STATUTES. WE ARE CONVINCED THAT THESE STATUTES PROVIDE SUFFICIENT AUTHORITY, DIRECTION, AND FLEXIBILITY FOR PROTECTION OF THE PUBLIC HEALTH AND THE ENVIRONMENT. AS THE AGENCIES SEEK TO APPLY THESE STATUTES WITHOUT UNDULY RESTRAINING INDUSTRIAL DEVELOPMENT, FURTHER RULE MAKING CAN PROVIDE ADDITIONAL REVIEW IF NECESSARY.

THE PROPOSED LEGISLATION WOULD ESTABLISH A BIOTECHNOLOGY SCIENCE RESEARCH PROGRAM IN OSTP. I BELIEVE THAT THE MANAGEMENT OF SUCH A PROGRAM IS AN INAPPROPRIATE AND DUPLICATIVE ROLE FOR OSTP. FEDERAL FUNDING FOR RESEARCH AND ITS MANAGEMENT BELONG IN THE VARIOUS AGENCIES.

For these reasons, we believe that H.R. 4452 is not needed and, in some respects, is inappropriate.

I must emphasize that we do not look at what we have done and conclude that our work is finished. Knowledge in molecular and cellular biology will continue to accrue very rapidly. As information is gained, it will affect how and what we regulate, and what can be exempted from regulation. The development of our regulatory approach is evolutionary, akin to the experience of the NIH Recombinant DNA Advisory Committee in amending its guidelines for the conduct of laboratory research.

That concludes my remarks, Mr. Chairman. Dr. David Kingsbury, Assistant Director for Biological, Behavioral and Social Sciences at the National Science Foundation has a supporting statement.

National
Science
Foundation

STATEMENT OF

DAVID T. KINGSBURY

ASSISTANT DIRECTOR
BIOLOGICAL, BEHAVIORAL, AND SOCIAL SCIENCES
NATIONAL SCIENCE FOUNDATION

BEFORE THE

SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH, AND ENVIRONMENT

AND THE

SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY

COMMITTEE ON SCIENCE AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

JUNE 4, 1986

Mr. Chairman and Members of the Subcommittees:

My name is David T. Kingsbury and I am the Assistant Director of the National Science Foundation for Biological, Behavioral, and Social Sciences. However, this afternoon I am here in my role as the Chairperson of the Biotechnology Science Coordinating Committee (BSCC), a position that I have held since the formation of the committee.

In this brief statement, I would like to focus your attention on some of the details of the formation and operation of the BSCC and make a few comments about the philosophical approach of the Committee. Finally, I will offer my opinion about the future of the BSCC and the wisdom of embedding it in statute as proposed in H.R. 4452.

The BSCC was established as an important part of the Administration's plan for a coordinated framework for biotechnology regulation. The concept of the BSCC evolved out of our original proposal of a strong and overriding Biotechnology Science Board (BSB) as announced in a December 1984 Federal Register notice regarding a proposed Coordinated Framework for Biotechnology Regulation. In response to very thoughtful public comments, and concerns within the Biotechnology Working Group, we chose to modify the BSB proposal. After considerable discussion we agreed on the establishment of the BSCC and structured it as an interagency coordinating committee under the Federal Coordinating Council for Science, Engineering and Technology (FCCSET). The BSCC charter and a brief discussion about the

Committee appeared in the first part of the Administration's final biotechnology policy statement, which appeared in the Federal Register on November 14, 1985.

It is gratifying, and somewhat flattering, to see that many Members of Congress share our views of the need, role and goals of the BSCC, as shown in H.R. 4452. We established the BSCC, which began operation in October 1985, to serve as an interagency coordinating group to address the scientific issues related to the regulation of biotechnology research and products. The Committee operates under guidance from its charter and a Memorandum of Understanding signed by each of the members. The Committee has met approximately monthly since its establishment and its initial activities have been principally the consideration of scientific issues which have arisen during the development of the Administration's Coordinated Regulatory Framework. The Committee has also discussed regulatory actions taken by member Agencies and has considered several multiagency proposals related to basic research, which have been submitted to the BSCC for an initial opinion and any recommendation for further action.

As I have stated to the Congress in earlier testimony, I am very pleased with the operation of the Committee and I firmly believe in its effectiveness. The discussions have been frank, open, honest and constructive. It is my opinion that this level of honest interaction and the positive, open, problem-solving attitude among senior agency officials has been the result of two factors. First, we have developed a solid and trusting relationship among the members of the Committee, and it is clear that the group has set its agenda and focused its deliberations in favor of the common good. Second, and more relevant to this discussion, we have established a rule that the committee consists of principals only and no member is allowed to send a representative in his place. This rule helps maintain the open and honest atmosphere of the meetings and is an assurance of the confidentiality of comments and exchanged information. In an environment in which a great deal of regulatory law is established by litigation, it is essential for a regulator to feel that planning and other predecisional discussions of agency science policy, problems or questions are held in a highly confidential environment. We feel that this principle is essential, that the BSCC must be a committee composed of senior government officials and not a public advisory committee with outside members, even if those members are appointed by the President. Each of the agencies involved in biotechnology regulation has (or very shortly will have) a public advisory committee on matters relating to biotechnology which operates under the Advisory Committee Act. Those committees are available to provide discussion, perspective and advice regarding specific issues as well as broader perspectives. The BSCC is needed to focus attention on a different set of problems, those practical scientific issues that are important in helping the regulators and reviewers make accurate assessments of potential risks. I do not wish to infer that the BSCC intends to do all of its business in private. One element of the BSCC charter, which we all felt was necessary if it was to serve its full function, is a call for periodic public meetings in order to give the committee the opportunity to hear the views of the public and to gather opinions from all parts of our society. Because the Committee was new and had many organizational issues to solve we have not had a public meeting as early as we had originally planned. At present we have reserved the Auditorium of the National Academy of Sciences for the morning of July 9, 1986 in order to hold our first public meeting. The meeting will be announced in the Federal Register well ahead of the planned date. We are looking forward to what we predict will be a stimulating morning.

My final comments will focus on the setting of research priorities and the identification of appropriate research topics. The BSCC has been presented with a number of research questions by various members of the scientific community. We have discussed these questions and the impact that various new research programs would have on agency research priorities. We all agree that research on questions relating to the environmental influence of genetically altered organisms is of high priority. However, each of the affected agencies has been able to place those priorities within the whole context of the agency's mission and other problems. It is an essential part of the national scientific effort that such priorities be set by the agencies and the Congress and that special single issue committees not be placed in the position of exerting undue influence. As a senior administrator in a major granting agency I am all too well aware of the existing groups attempting to exert such influence and it would be very difficult to balance these demands with another group which had a statutory standing. The agencies have responded to the need for research in the area of environmental biology. For example, this is the fastest growing area in the biological sciences at NSF, with the exception of a special instrumentation program. We anticipate that this high priority will be maintained into the future.

In summary, I feel that the changes in the structure and operation of the BSCC and its freedom to set the type of research priorities that fit the broad functions of the individual agencies, as they are proposed in H.R. 4452 would have a serious negative impact on this currently effective committee. For this reason I am opposed to this legislation.

Thank you for this opportunity to appear at this hearing and express my views. Of course I will be pleased to try to answer any questions you may have.

Mr. **Scheuer**. We'll now move to the next panel: Dr. Moselio Schaechter, president of the American Society for Microbiology and professor and chairman of the Department of Molecular Biology at Tufts University, accompanied by Dr. Monica Riley, chairman of the Committee on Genetic and Molecular Microbiology of the Public and Scientific Affairs Board of the American Society for Microbiology. They'll also be joined by Dr. Michael Goldberg who is president of the—who is executive director of the American Council on Microbiology.

Dr. Schaechter, you are the spokesman for the group?

STATEMENT OF DR. MOSELIO SCHAECHTER, PRESIDENT, AMERICAN SOCIETY FOR MICROBIOLOGY AND PROFESSOR AND CHAIRMAN OF THE DEPARTMENT OF MOLECULAR BIOLOGY, TUFTS UNIVERSITY, ACCOMPANIED BY DR. MONICA RILEY, CHAIRMAN, COMMITTEE ON GENETIC AND MICROBIOLOGY OF THE PUBLIC AND SCIENTIFIC AFFAIRS BOARD OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, AND MICHAEL GOLDBERG, EXECUTIVE DIRECTOR, AMERICAN COUNCIL ON MICROBIOLOGY

Dr. **Schaechter**. Yes, sir. Thank you very much.

Mr. **Scheuer**. All right. Pardon?

Dr. **Schaechter**. Thank you very much for the opportunity to come here and testify this afternoon.

Mr. **Scheuer**. Right. Why don't you—your statement will be printed in full at this point in the record. Why don't you take your 7 or 8 minutes and chat with us briefly and informally about hitting the highlights of your position, and then I'm sure we'll have some questions for you.

Dr. **Schaechter**. OK. Thank you very much.

In our testimony we intend to address the following issues related to the bill: In the first place, the proposal to establish the biotechnology science research program; secondly, the definition of genetically engineered microorganisms; thirdly, the category of genetically engineered microorganisms which could be scrutinized and those which might be exempt from further scrutiny; and, fourth, some of other provisions of the bill H.R. 4452.

In the way of background, I'm not sure very much is necessary, but it's obvious that we support the steps that have been taken, that are being taken, to exercise prudence and caution in handling organisms intended for introduction into the environment.

Mr. **Scheuer**. Excuse me. Could you pull the microphone a little bit closer? Speak right into it.

Dr. **Schaechter**. Yes, sir. OK. Thank you very much.

Mr. **Scheuer**. If you drop your voice, I have trouble hearing.

Dr. **Schaechter**. All right.

Mr. **Scheuer**. Just pull it up close.

Dr. **Schaechter**. OK. Thank you.

In supporting the caution and prudence that is being suggested, we also like to point out that it's important to maintain a sense of perspective so as not to impose unnecessary obstacles either in basic research or in commercial applications.

The current debate and the current interest in biotechnology is reminiscent of the original debate that took place about 10 years ago in regard to the recombinant DNA research. At that time the NIH established a committee called the Recombinant DNA Advisory Committee, RAC. And since its inception and since the beginning of genetic engineering with microorganisms, there have been no laboratory manipulations or accidents which have caused harm to workers or to the environment. Thus, we urge that regulations be considered in the context of extensive experience that has been gained through the aegis of RAC.

Now what we learn from the process used in regulation of recombinant DNA research is that the original guidelines can be stringent and to some overly cautious, but they should be formulated in such a way they can be relaxed quickly as the information permits.

Mr. **Scheuer**. They can be relaxed?

Dr. **Schaechter**. Relaxed quickly as new information becomes available.

Mr. **Scheuer**. Right.

Dr. **Schaechter**. Let me again go into the various points of the bill about which we would like to comment.

With regard to the Biotechnology Science Research Program, we agree, as you've heard earlier by others, that there is a basis for making risk-management decisions, but that deficiencies do exist in our knowledge in some areas. Therefore, we endorse the concepts of a scientific research program which deals with generation of risk assessment methodology, and we recommend that the Health Effects Institute of Boston is a good model to follow in developing a sound research base for regulatory decisionmaking. This institute is jointly supported by EPA and the automobile companies to study the health effects of automobile emissions.

This joint Government-industry funding and the public process by which research studies are selected and monitored has made reports of this group very critical. The mechanism has proved economical and it has lessened anxiety over regulations. It has established a partnership between regulatory agencies and the scientific communities.

We believe it's timely to develop a similar institute in the biotechnology community, especially for the study of release of engineered organisms to the environment. The American Society for Microbiology is willing to assist in the establishment of a Biological Effects Institute, and we are presently discussing how we can play an integral role in conjunction with other groups in order to implement this concept.

We would like to bring to the subcommittee at a later date a proposal that would attempt to address some of the very important practical questions associated with the establishment of such an institute.

From our perspective, in order to maintain the integrity and credibility of such an institute, it must be freestanding and independent.

And we look forward to working with the subcommittees on this venture.

My next point deals with the categories of microorganisms subject to review. Recently a committee of experts within the American Society for Microbiology was convened to develop a response to the specific questions which were posed in your letter of invitation.

Regarding whether the definition of genetically engineered organisms proposed in the bill is sufficient to include all organisms which should be subject to review, it was the consensus of the committee that the definition should include not only all intergenerically created microorganisms, but also all microorganisms that are pathogens and their derivatives.

We emphasize that this should be subject to scrutiny by a panel of experts on a case-by-case basis as candidates for regulation. We also believe that in these classes of microorganisms no distinction should be made between regulatory genes or genes calling for gene products.

As individual cases are screened by expert panels over a period of time, experience would lead to generalizations. Ultimately guidelines will be revised and categories of microorganisms will be listed as exempt from regulation, much like the system used by the RAC.

Next a few words about the categories to be excluded from review: we favor the exclusion of microorganisms made by intrageneric, as opposed to intergeneric, manipulation, and those which are derived from nonpathogens. By exclusion, we do not mean exemption from the established regulatory process for products to be introduced into commerce.

There are many, many examples of nonpathogenic microorganisms that have been genetically altered by one technology or another. Some of these technologies are new; some are very old, and which have been released into the environment without the deleterious effects to man, other animals, or plants.

Examples are fermentations of natural foodstuffs which have been conducted since antiquity. Undoubtedly mutants were selected spontaneously to yield higher alcohol content in yeast fermentation or increase acidity in cheese fermentation.

In more modern times introduction of antibiotics, aminoacids, steroids, organic acids, and so forth, by the use of microorganisms has involved mutation programs to either increase the yield of products or to confer resistance to bacteria failures.

Many of the spent cultures after use are considered byproducts of the manufacturing process and are either sold as fertilizers or disposed through local sewage treatment plants. No harm has resulted from this practice.

In addition, cells which have been altered genetically are usually metabolically handicapped and not efficient competitors in nature.

We also would like to make a point that we are not aware of any instance of change by genetic manipulation of a nonpathogenic microorganism into a pathogen.

Last, the regulation of the microorganisms. The regulations being formulated should apply to the microorganisms, not to the way the microorganism is manufactured. Genetic methodology includes techniques such as genes transfer, gene splicing, microinjection of DNA, and so forth. And we find that that is not relevant to the issue of regulation.

Many organisms that are genetically altered in the research laboratory would not differ from naturally occurring genetic variants and would pose no more threat to the environment than natural variants. What we really should be concerned about is the creation of pests, not how they have been created.

In addition to these statements, we have—we don't find we're in a good position to comment on the bill at this time, but we would like to make some general statements.

We believe that case-by-case approaches should be adopted until more experience and scientific knowledge is developed in the area. We also believe that in future legislation or rules or regulations mechanisms can be found to make certain that the agency implementing the regulation will be that which has the greatest expertise for performing the function. We believe that in some cases more than one agency should be involved for a single project because some proposals would have overlapping implications. But it's important to designate one agency as bearing the primary responsibility.

We concur that a discussion of the risk benefits should accompany any application, and we agree that the burden of providing information relevant to the claims of safety should lie with the applicant.

It should be understood, however, that it is not possible scientifically to prove a complete absence of hazard. Zero risk does not exist.

There is a number of other provisions about which we comment which are in our written testimony, and I won't go into those now.

In summary, in conclusion, I would like to say that we have articulated some fundamental principles. For instance, we should learn from previous experience in regulating microorganisms such as that which has been gained from NIH's RAC. The regulation of biological entities should consider only the organisms, not the process whereby they have been made.

Microorganisms should be regarded on the basis of their history as pathogens or pests or in their potential for becoming pathogens or pests. We're willing to continue to provide the expert opinions of the members of the American Society of Microbiology to the Congress. We wholeheartedly support your attempts to provide a safe environment for our citizens. We ask you to provide the safeguards on the basis of the best available scientific data.

Thank you very much, Mr. Chairman.

[The prepared statement of Dr. Schaechter follows:]

STATEMENT BY MOSELIO SCHAECHTER, PH.D., TUFTS UNIVERSITY

PRESIDENT, AMERICAN SOCIETY FOR MICROBIOLOGY

BEFORE THE HOUSE SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT
AND THE
HOUSE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
HEARING ON
HR 4452 "THE BIOTECHNOLOGY SCIENCE COORDINATION ACT OF 1986"

JUNE 4, 1986

TESTIMONY
of the American Society for Microbiology
before the
House Subcommittee on Natural Resources, Agriculture Research
and Environment
and the
House Subcommittee on Science, Research and Technology
June 4, 1986

Mr. Chairmen and members of the subcommittees, my name is Moselio Schaechter and I am President of the American Society for Microbiology (ASM). I am accompanied by Professor Monica Riley, Chairman of the Committee on Genetic and Molecular Microbiology of the ASM's Public and Scientific Affairs Board (PSAB) and Dr. Michael Goldberg, Executive Director of the ASM. We thank you for giving ASM the opportunity to testify at this hearing on HR 4452, "The Biotechnology Science Coordination Act of 1986." In our testimony we intend to address the following issues directly related to the bill: 1) the proposal to establish a Biotechnology Science Research Program (BSRP), 2) the definition of a genetically engineered microorganism, 3) the categories of genetically engineered microorganisms and their products which could be scrutinized as candidates for regulation by federal agencies, as well as those categories which will probably not cause deleterious health or environmental consequences and can be excluded from further scrutiny, 4) and certain other provisions of HR 4452. We also will place the current efforts to regulate the products of genetic manipulation in the broader historical framework.

Genetic Manipulation of Microorganisms

The emergence of exciting new tools over the last decade in the area of biotechnology has opened avenues for basic discoveries, and opportunities for applications in the areas of agriculture, medicine and others. Microbiologists are now capable of fine tuning the generation of genetic variants at a level of detail in design and execution that had not been thought possible previously. Some of the new genetic constructs will be used in the research laboratory, others will be used in the industrial fermentor or in the out-of-doors environment.

We support the steps that have been taken and are being taken to exercise prudence and caution in handling organisms intended for introduction into the environment. However, we believe that it is important to maintain a sense of perspective and not to impose unnecessary obstacles to either basic research in biotechnology or in its commercial applications. International competition will continue to be intense in this area. The mechanisms of regulation of biotechnology to be employed in the U.S. ideally should not be cumbersome or burdensome. Instead they should be simple, effective and expeditious. We must avoid over-regulation, which could deprive our society of the benefits of this new technology and could drive research and development into other countries where it might be done less well and/or less safely.

It should be recognized at the outset that some products of the newer metholodogies, like their predecessors, may well affect the environment in some way. The impact of additives on the environment is not static but is controlled by many different physical and chemical factors, which are always changing. Despite the magnitude and complexity of the variables that operate in the environment, we are able to make management decisions that minimize risk to man and the environment. However, it is necessary to guard against those who would use dynamic complexities in ecosystems as excuses to impede progress or to stifle introduction of new products which have the potential to enhance the quality of life in many ways.

The current interest in biotechnology is reminiscent of the original debate 10 years ago concerning regulation of recombinant DNA research. Based on the concerns of the American Society for Microbiology, along with other scientific societies, government agencies and the Congress, the National Institutes of Health (NIH) established the Recombinant DNA Advisory Committee (RAC). Since RAC's inception there have been no laboratory manipulations or accidents which have caused harm to workers or the environment. We strongly urge that regulation be considered in the context of the extensive experience that has been gained by the successful operation of the NIH RAC. We should learn from the process used in regulating recombinant DNA research in which the original guidelines were overly cautious and conservative but were deliberately designed to be relaxed quickly as new information permited. We believe that in formulating oversight mechanisms, each agency must establish flexible requirements which can be modified and relaxed as circumstances warrant and experience dictates.

Federal agencies, including EPA, USDA and FDA, are about to publish their policies for a coordinated framework for regulation of biotechnology. It is imperative for all interested parties to review the revised policy statements, determine how the new regulatory process for biotechnology products will be administered, and assess regulatory deficiencies. Effective coordination among agencies and implementation of existing authorities may likely mitigate the need for new legislation of the kind that is being proposed.

The Biotechnology Science Coordination Act of 1986

We will comment in this section on a number of the major provisions of HR 4452.

1) Biotechnology Science Research Program

The ASM recognizes that although there is a basis for making risk management decisions on products employing the new genetic methodologies, deficiencies exist in our knowlege in some areas. We, therefore, endorse the concept of a scientific research program which deals with the generation of risk assessment methodology that can be applied generally as well as to biotechnology specifically. We would recommend that the "Health Effects Institute" of Boston is a good model to follow in developing a sound research base for regulatory decision-making. The HEI is jointly supported by EPA and the automobile companies to study the health effects of automobile emission. It takes no position on emission standards. The joint government/industry funding and the public process by which research studies are selected, monitored, and evaluated, makes its studies credible. This mechanism has proven not only economical, it has lessened anxiety over regulations and established a partnership between the regulatory agencies and the scientific communities. We believe that it is timely to develop a similar institute in the biotechnology community - especially for the study of release of engineered microorganisms to the environment. The ASM is willing to assist in the establishment of a biological effects institute and is presently discussing how it can play an interim role in conjunction with other groups in order to implement this concept. We would like to bring to the subcommittees at a later date a proposal that would attempt to address some of the very important practical questions associated with the establishment of such an institute. From the Society's perspective, in order to maintain the integrity and credibility of the institute it must be a freestanding and independent organization. We look forward to working with the subcommittees on this venture.

2) Categories of Microorganisms Subject to Review

Concerning the scientific aspects of HR 4452, a committee of experts within the ASM consisting of members experienced in molecular biology and genetics, environmental microbiology, microbial physiology, and agricultural and industrial microbiology, was convened to develop a response to the specific questions which were posed in your letter of invitation. A consensus of that committee forms the basis of the expert testimony which is being provided here today.

Regarding whether the definition of genetically engineered microorganism proposed in the bill is sufficient to include all the organisms which should be subject to review, it was the consensus of the committee that the definition should include not only all intergeneric microorganisms but all microorganisms that are pathogens and their derivatives. These should be subject to careful scrutiny by a panel of experts on a case-by-case basis as candidates for regulation. The committee also believes that in these classes of microorganisms no distinction should be made between regulatory genes or genes coding for gene products. The basis of the committee's opinion is inherent in the examples which follow.

We are aware that introduction of foreign regulatory sequences in order to regulate specifically a gene of interest will in most cases be entirely innocuous. Nevertheless, we favor not making a distinction between coding and noncoding sequences. Strain construction that places a strong, effective regulatory sequence in a position of control over any particular gene can increase the expression of that gene many fold. This can influence rates of synthesis of key structural proteins that may affect a microorganism's capacity to compete and survive in natural environments.

For instance, if the gene whose expression is augmented codes for a toxin, the action of the regulatory sequence could cause a problem of increased toxin production that could overwhelm natural defenses. Another example could involve expression of oncogenes, which are normally quiescent, but whose awakening and expression may be the event that triggers the cancerous state.

The committee also recommends that microorganisms that are intergeneric or derived from pathogens should be subject to the same scrutiny regardless of whether they are manufactured via recombinant DNA, cell fusion, or microinjection techniques.

As individual cases are screened by expert panels over a period of time, experience will lead to generalizations . Ultimately guidelines will be revised and categories of microorganisms will be listed as exempt from regulation, much like the system used by the RAC.

3)Categories Excluded from Review

We favor the exclusion of microorganisms made by intrageneric manipulation and those that are derived from known nonpathogens. By exclusion we do not mean exemption from the established regulatory process for products to be introduced into commerce. The basis of this recommendation is our vast experience with all of these types of microorganisms.

There are a myriad of examples of nonpathogenic microorganisms that have been genetically altered by one or another technology and have been released into the environment without deleterious effects to man, other animals or plants. As an example, the fermentation of natural food stuffs has been conducted since antiquity. Many of the "mother cultures" were selected for their improved qualities of taste or nutrition. Undoubtedly, mutants were selected spontaneously to yield higher alcohol content in yeast fermentation, or increased acidity in cheese fermentations.

In more modern times, the production of antibiotics, amino acids, steroids, organic acids, etc., by the use of microorganisms has involved mutation programs to either increase yields of products or to confer phage resistance. The mutation programs were empirical at the onset. As a better understanding of the biochemical processes and control mechanisms became available, they shifted to the more precise method of directed mutation. Many of the spent cultures are considered by-products of the manufacturing process, and are sold as fertilizers or disposed through the local sewage treatment plants. No harm has resulted from this practice.

Usually, cells which have been altered genetically are metabolically handicapped and not effective competitors in nature. Microorganisms used as additives to the soil do not usually persist. Attempts to add microorganisms 1) to soil to improve plant productivity or resistance to pests; 2) to sewage to improve waste water treatment; 3) to the sea to degrade oil slicks are usually not successful unless the organisms are added continuously. They will only persist if they have an inherent selective advantage or if some physical or chemical environmental condition is changed to give them that selective advantage.

It is important to be aware that there is no known instance of change by genetic manipulation of a nonpathogenic microorganism to one that is pathogenic.

4) Regulating the Microorganism

The regulations being formulated should apply to a microorganism, not to the way the microorganism is manufactured. Genetic methodology includes techniques such as gene transfer, gene splicing, microinjection of DNA, nuclear transplantation, or cell or embryo fusion. Many organisms that are genetically altered in the research laboratory will not differ either qualitatively or quantitatively from naturally occuring genetic variants and will pose no more threat to the environment or to mankind than do natural variants. Nevertheless, some of the organisms that are altered in the laboratory could conceivably be novel in ways that would lead to harm, perhaps through perturbation of an ecosystem. It is these potentially harmful microorganisms that one wishes to identify and to control, not the processes by which they were made. What we really should be concerned about is the creation of "pests" not how they are created.

5) Genetic Alterations

Genetic alterations can significantly change a microorganism and influence its activities and interactions. However, the committee is not aware of any genetic alteration of nonpathogens which adversely influences the interactions of these microorganisms with their environment. From a theoretical perspective, the addition of anything to the environment, physical, chemical or biological, will cause some change. The question is not whether a change occurs but the nature, degree and duration of the change. Microorganisms are added daily to the environment in large quantities. They are introduced by man, by animals, by the food processing industry, and by waste disposal systems. These microorganisms generally don't persist and it can be expected that engineered microorganisms will experience a similar fate. Indeed they are less likely to persist than nonengineered microorganisms. At this time no one has identified the factors that permit persistence of organisms added to the environment and no one has the knowledge necessary to increase their survival.

6) Correcting Regulatory Deficiencies

The ASM does not believe that it would be constructive to comment in detail on regulatory deficiencies in HR 4452 before publication in the Federal Register of revised statements of policy and procedures by the EPA, USDA and FDA. Generally, with regard to federal policy guidelines, we believe that a case-by-case approach should be adopted until more experience and scientific knowledge is developed in this area. We also hope that in any future legislative proposals, rules or regulations a mechanism can be found to make certain that the agency implementing the regulation will be that which has the greatest expertise for performing that function. We also believe that in some cases more than one agency should be involved for a single project in order to examine properly proposals that have overlapping implication. We agree that it is important to designate one agency as bearing primary responsibility. We concur that a discussion of risk/benefit should accompany an application and we agree that the burden of providing information relevant to claims of safety should lie with the applicant. It should be understood, however, that it is not possible scientifically to prove a complete absence of hazard. Zero risk does not exist.

In reviewing HR 4452 we are concerned about a number of provisions. We believe that reasonable time limits for a response from the Administrator to various phases of applications for permits should be mandated. We believe that the microorganisms used to manufacture products should not be covered by these regulations if they are used in a contained facility, and if the wastes of the process of manufacture are sterilized before release to the environment. We are concerned that publication of information regarding release in newspapers may cause undue public anxiety and delay. The intent of this provision might be achieved more effectively by mandating that state, county, and municipal regulatory agencies be alerted of the impending release. The bill also mandates in statute the existence of the Biotechnology Science Coordinating Committee (BSCC), which has already been established administratively. A decision concerning whether or not it has to be authorized in law or whether it should continue to operate on an administrative basis seems premature. The ASM prefers to defer judgement until we see how the new regulatory framework evolves.

Summary

In commenting on the bill and on general approaches to regulating the release of microorganisms generated by applied genetics, we have articulated some fundamental principles:

- We should learn from previous experience in regulating microorganisms such as that gained from NIH's RAC;
- Regulation of biological entities should consider only the microorganisms, not the process whereby they are made;
- Microorganisms should be regulated on the basis of their history as pathogens or pests or on their potential for becoming a pathogen or pest

In addition, we have provided for your consideration categories of microorganisms that should be subject to careful scrutiny by federal agencies as candidates for regulation. We have also described categories of microorganisms which most probably will cause no deleterious effects to the environment. We intend to continue to monitor the scientific and technical literature and to provide the Congress and the federal regulatory agencies with our assessments of these developments. We are willing to provide the expert opinions of ASM members to the Congress. We wholeheartedly support your attempts to provide a safe environment for our citizens. We ask you to provide these safeguards on the basis of the available scientific data.

Mr. **Scheuer**. Thank you very much.

Congressman—Congresswoman Schneider.

Miss **Schneider**. One of the questions that comes to mind immediately is I'm just wondering if it's scientifically valid to maintain organisms created by gene deletions and if that's significantly different from organisms from which they were derived. Is there a distinction there?

Dr. **Schaechter**. I believe that to argue about those distinctions at this time in the absence of the published regulations makes it very difficult. My offhand—I can give you a personal opinion that most deletions—most deletions, perhaps all—should be considered to be something very similar from the organisms from which they were derived. But, as I say, it's—I would take the question in context. Perhaps we'll have to come back when the regulations are published.

Miss **Schneider**. That's part of the difficulty with some of the questions that I had in mind.

I think that at this time I'd like to pass on some of my other questions, Mr. Chairman. Thank you.

Mr. **Scheuer**. Congressman Volkmer.

Mr. **Volkmer**. Yes; I have several questions, Dr. Schaechter.

Is it scientifically valid to maintain that organisms created by gene deletions are not significantly different from the organism from which they were derived?

Dr. **Schaechter**. Well, they're part of the same question I just got, I think.

Mr. **Volkmer**. I know.

Dr. **Schaechter**. And I think the answer would have to be the same. We can give you an offhand answer, which is that—seen in isolation, the answer of the statement is correct, that they're not really different. However, in the context of the regulations, one has to really look at the regulations themselves.

Mr. **Volkmer**. Well, does it make any difference that the organism is pathogenic or not?

Dr. **Schaechter**. Potentially, yes. So that no statement of that sort can be all encompassing. In other words, if you ask me, is it always true, the answer is, no; it's not always true. Most of the time it's true.

Mr. **Volkmer**. Well, that's what I wanted—whether it was always true, and that is not true?

Dr. **Schaechter**. But nothing is always true.

Mr. **Volkmer**. That's correct; right.

Dr. **Schaechter**. In microbiology except for the statement. [Laughter.]

Dr. **Riley**. I think what we recommended here is that all pathogens be scrutinized as possibly being subject to regulation, with or without deletions. So all pathogens, we believe, and all intergeneric constructions should be examined for whether they should be regulated, and that means any deletions among those groups.

But a nonpathogen that has sustained a deletion we believe does not constitute the kind of potential risk that would require that it be scrutinized.

Mr. **Volkmer**. Would it be worthwhile, though, for, say, a notice to be given that even a nonpathogen with a gene deletion is going to be released, at least a notice of that, or not even that?

Dr. **Riley**. Not even that because it's our position that there are organisms that have been mutated and used in commerce and agriculture, in food production, in pharmaceutical production, and so forth, that have those constitutions. So that either one backs up and examines organisms from antiquity to today that are used in making champagne and cheese, and so forth, or one takes the position that that category of organism in human affairs would have no examples of anything going awry by using that category of mutated organism. So we see no difference between that category of organism as brought about in this new era and that same category of organism as used from antiquity to the present.

Mr. **Volkmer**. Now if an organism produces a protein which confers a competitive advantage on the organism and a gene regulating the production of this protein is altered, could the interaction of this organism in the environment be altered?

Dr. **Schaechter**. I think the answer goes—again, we would categorize the organism as being a known pathogen or not.

Mr. **Volkmer**. Well——

Dr. **Schaechter**. And that would be the way in which we would make the distinction. That is, if it's a nonpathogen, then we don't see that there's any reason for concern. If it is a pathogen, if it were—if a pathogen is involved, then there are forms of risk assessment which one can develop and has developed already.

Mr. **Volkmer**. And so if it was—the question, then, relates still to whether it's pathogenic or not?

Dr. **Schaechter**. That's right. Yes, sir.

Mr. **Volkmer**. All right.

Miss **Schneider**. Would the gentleman yield on that point, please?

Mr. **Volkmer**. Yes.

Miss **Schneider**. The risk assessment that you're referring to, how do those differ from agency to agency?

Dr. **Schaechter**. Well, I think they're very different in regard to organisms which have to be deliberately released over soil or organisms which are to be used in a fermenter, for instance.

FDA is concerned largely with organisms which are—which make a product in a fermentation tank. That is a confined environment and can be sterilized. There's no need to be as concerned with that because the product of the fermentation is what one wants, not the organism itself. Obviously if one spreads living organisms in the environment over a field, the questions are different and risk assessment has a different nature.

Miss **Schneider**. Well, I was looking through some of the other examples of the difficulties with various agencies making different determinations, risk-assessment determinations. I'm wondering, Would this particular piece of legislation help or have any impact on such clarification? The thing I'm thinking of is that in one particular case there were two agencies within the Department of Agriculture that treated applications for similarly genetically engineered products in completely different manners. Now I would think that risk assessments ought to be standardized enough within the Department of Agriculture so that that sort of determination would not be taking place.

Dr. Schaechter. Well, I hate to weasel again, but not knowing what USDA is proposing and not knowing what the other agencies are proposing, I cannot say that their proposal is faulty because it's not available to us yet.

Miss Schneider. Well, how about as it is currently practiced?

Dr. Schaechter. I believe there is room for improvement. [Laughter.]

Miss Schneider. Thank you. I yield back.

Mr. Scheuer. Congressman Volkmer.

Mr. Volkmer. Yes. I'd like to—well, first let me ask you, Dr. Schaechter, whether you would feel comfortable answering a question with regard to USDA and their plants and animal type of operations?

Dr. Schaechter. Well, again, sir, if I may, if it refers to the regulations which they are about to publish, then I can't.

Mr. Volkmer. Well, let's not say that it refers to regulations. Let's get to a matter that I think came up right here. Would you be able to define what releasing into the environment is?

I'll give you the reason for that. We had a hearing and they say if you give a vaccine shot into an animal, that's not a release into the environment. There's a question whether the animal will shed some of the product or not. We also had hearings back in March where inoculations into a tree outside, just like outside, would not be released into the environment. Now other people disagree with that.

Dr. Schaechter. I would too, sir.

Mr. Volkmer. You would say that is a release——

Dr. Schaechter. If I can't autoclave it, it's in the environment. [Laughter.] Mr. Volkmer. If what?

Dr. Schaechter. I'm sorry if I used a technical term. [Laughter.]

Mr. Volkmer. Right.

Dr. Schaechter. If you can't sterilize it, then there is a risk that can spread in the environment.

Mr. Volkmer. Right.

Dr. Schaechter. I think it's quite correct.

Mr. Volkmer. So, in other words, you would support in this regard—we've had difficulty in this area in the regulation as to what is released into the environment, but it would be your premise that any definition should be broad enough to cove any type of release?

Dr. Schaechter. Yes, sir, but I would—may I take you to the next logical step?

Mr. Volkmer. Yes.

Dr. Schaechter. There are types of releases and types of releases. If one were to take a county full of strawberries and release organisms overnight, that's quite a different dimension and quite a different concern than if one were, in fact, inoculating animals in a confined environment. Those things——

Mr. Volkmer. In a confined environment, but not to say whether you're inoculating 1,400 animals in a nonconfined environment?

Dr. Schaechter. That's quite different.

Mr. Volkmer. That's a little different; that's correct.

Dr. **Schaechter**. Dr. Riley would like to comment.

Dr. **Riley**. If I could just add a little something on that as far as inoculating animals go with a vaccine, let's say, that might be a live virus—that I believe the physiology and biology differs one example to another and that there are some physiological situations where the inoculated animals will be putting out live virus just as they were given it, either, you know, from a runny nose or whatever, but in other types of physiological situations the place where the virus goes is really sequestered; it may be along nerve shafts, and so forth, and they do not come out again, so that there would be—in my way of thinking there might be possibility of inoculation with a vaccine to animals where it really constitutes virtually no risk because of the physiology. So I think that has to be examined and that's part of the risk assessment chore—is to look case by case and to decide whether this is one that proliferates and spreads or this is one that just goes to ground as soon as you've inoculated the animal.

Mr. **Volkmer**. All right, but I agree that as far as risk assessment that is necessary, but where I see some of our difficulty in what we've had in the development of this regulation of the biotechnology field so far is this trying to get a definition where everybody agrees or bring it out as to what is released into the environment.

Dr. **Riley**. What is released; that's true.

Mr. **Volkmer**. We also have a question of—and I don't know if you want to address that or not—but whether when we got into, again, the live vaccine for pseudo-rabies, the question of what is the recombinant DNA procedure and what is not, or a product of it.

Dr. **Schaechter**. Well, if I may comment on that——

Mr. **Volkmer**. Yes.

Dr. **Schaechter** [continuing]. I think that that's quite irrelevant. The reason is that if you're concerned with the effects of genetic manipulation, it's the organism you want to worry about, not how it was derived. So I think that it's essentially a waste of time to do that.

Mr. **Volkmer**. I think it's clear from your statement that it's the product, the end product, that we should concern ourselves——

Dr. **Schaechter**. Yes.

Dr. **Volkmer** [continuing]. Not the methodology which brought it about.

Dr. **Schaechter**. Yes.

Mr. **Volkmer**. Thank you very much, Mr. Chairman.

Mr. **Scheuer**. Thank you, Mr. Volkmer.

Congresswoman Jan Meyers of Kansas.

Mrs. **Meyers**. Dr. Schaechter, I would like—we have not had accidents in the past with genetically-engineered microorganisms, have we?

Dr. **Schaechter**. Not to my knowledge, ma'am.

Mrs. **Meyers**. And in your estimation is this because there has not been a lot of experimentation taking place or because we have operated with extreme caution and care?

Dr. **Schaechter**. I have read an estimate that something 1.5 million genetic crosses have been performed using recombinant DNA technology—known numbers. These have been—were carried out originally under conditions of great stringency, but under the relaxation of the guidelines of NIH, or RAC, they were carried out essentially on the bench dock.

So the reason that nothing has happened is not because of the containment and the care that has been exercised but rather because intrinsically there seems to be a very low probability of there being anything dangerous about this, these manipulations.

Mrs. **Meyers.** And still, because that probability exists, there would have to be a great deal of care exercised?

Dr. **Schaechter.** Well, if I may say so, it's—the reason why these hearings are being held is I think that we're stepping out from the concerns about which we now regulate, the research laboratory, into essentially the field. And there are differences in risks involved between manipulations on essentially a small scale in a relatively confined environment versus what happens when one once goes out in the field. So I think it's for that reason that these considerations are important.

My feeling is that, again, the magnitude of the risk can be easily overestimated. From what we know, there are ways of assessing these risks even in connection with release into the field.

Mrs. **Meyers.** Do you think that there's a fear on the part of the public about this, around this whole issue?

Dr. **Schaechter.** Yes, ma'am, a great deal.

Mrs. **Meyers.** Probably one of the reasons that there is some concern on the part of general public is that they have seen in the past that projects that we undertake and they are surrounded with great caution and a real emphasis on safety, and then as we get so we take the process more for granted we relax more and that's when accidents occur.

How can you maintain or would this be—how can you maintain that emphasis on care and caution, so that the mind of the public can be put at rest?

Dr. **Schaechter.** Let me make a couple of points related to that. In the first place, I think that, speaking from the point of view of a professional scientific society, one has to maintain the highest level of ethics and speaking the truth that one can. One should not be swayed by other considerations insofar as is possible. I think that essentially this is one of the voices that ought to be heard; it's not the only one.

I think, in addition, that a great deal of education is needed. Anybody can back themselves into a corner of horrors and think about gruesome things that can crawl out of test tubes—it's very easy to do—it's very hard to do that if one has a knowledge of biology or a knowledge even of logic.

And I say that advisedly it seems to me that all the constructs of the mind that deal with the creation of horrible things that can happen have been done on the basis of no knowledge. This is not to say that in the past there haven't been accidents which were carried out under conditions that today would be very difficult to imagine. We are gnawed by gypsy moths and kusu vines, and so forth.

Now, all the things could not happen today. There are regulations to prohibit that. And, in fact, what we know about gypsy moths—if somebody came today and said, "I'm going to release gypsy moths all over the place," there would be questions asked that were not questions at the time when this happened.

Therefore, I don't think that the analogy is a very good one. I think the public has to be somehow helped in their education to understand the difference and the actual, factual details that go into this.

So it's a question of honesty on the part of those of us who have to speak and willingness to educate the public insofar as the reception of this.

Mrs. **Meyers**. What is the most immediate foreseeable benefit that you can see from this?

Dr. **Schaechter**. Well, it depends. I think that in the area of medicine there are compounds which are being made, hormones and antiviral compounds like interferons which are not available by any other means. Those are products of biotechnology.

The same is true for vaccines. In fact, if I may dwell on it for 1 second, there is a possibility of creating a vaccine which would vaccinate against 10 or 12 different diseases of childhood at the same time. That vaccine does not exist as yet, but the possibility of a vaccine of that sort which can be administered throughout the world with the same ease as smallpox vaccine, because that's in fact what it is—it's a modified smallpox vaccine—that boggles the mind. That is an incredible possible advance.

You know that we have eradicated smallpox from the face of the Earth through vaccination. We stand a chance of doing this for another dozen or so killer diseases of mankind. And perhaps I should stop there because nothing beats that. [Laughter.]

Mrs. **Meyers**. Thank you, Mr. Chairman.

Mr. **Scheuer**. Mr. Ritter.

Mr. **Ritter**. Thank you, Mr. Chairman.

Where are—by the way, Jan Meyers' talking about what are the great potential breakthroughs and your answer, you mentioned vaccines, and I immediately thought about all the vaccines that we're not producing in this country any more because of the liability questions. I think we now have two companies producing vaccines in the United States.

And that led me to the next thought, which was the international competitiveness aspect of biotechnology. Where are our competitors with regard to this field in the sense of regulating its emergence? How's Japan working on this issue? How's England working on this issue? How's the Federal Republic of Germany actually working on this issue?

Dr. **Schaechter**. I'm sorry, I cannot give you very concrete answers because I haven't followed this recently. In regard to recombinant DNA guidelines, they have certainly followed what RAC has done. We have been the model for the world with regard to regulations for recombinant DNA, technology and regulations.

With regard to other forms of biotechnology, I'm not prepared to say, sir.

Mr. **Ritter**. Are Government regulatory schemes such as the one we are discussing here in the works at all? Are we about to witness this happening in a worldwide——

Dr. **Schaechter**. Dr. Riley may know.

Dr. Riley. No, I don't really know specifically other than just the general statement that in Japan these sorts of regulations are being developed, I believe, by their Government, what corresponds to their federal government.

Dr. Schaechter. What can be said with certainty is that we're being looked at, all of us, in this process.

Dr. Riley. Yes. There are consortia in Japan of Government-commercial interests where—and not separated as they are in this country, and that consortium is essentially regulating itself.

Mr. Ritter. Let me ask a variant on that question. Are there other precedents in the scientific—in the history of the scientific process that this kind of process relates to? Are there other regulatory schemes for the evolution of a new science that are anywhere near what we are discussing for this? Are we breaking new ground here?

Dr. Schaechter. Sir, I believe that the best analogy is that of the recombinant DNA guidelines, which are a research-oriented set of guidelines dealing with analogous questions. I find that that is a direct precedent and one that——

Mr. Ritter. That's research oriented.

Dr. Schaechter. Yes, sir, but the issues of risk assessment and how you deal with these questions were well spelled out——

Dr. Ritter. But we have a much better ability to deal with research questions—in terms of regulatory issues, we have a much better ability to deal with research questions than we do with questions involving corporate America commercial products, the introduction of new technologies into the environment.

Dr. Schaechter. Unfortunately, I'm not an expert on any subject other than perhaps the one I'm talking about. [Laughter.]

Mr. Ritter. Let me ask you a question about risk assessment. Jan Meyers asked about the kind of assurances that the public needs. Can risk assessment in that it is not a well-developed science—can risk assessment provide some of that assurance? Can we better risk assessment in order to provide greater assurance?

Dr. Schaechter. Yes.

Mr. Ritter. Where do we stand——

Dr. Schaechter. I'm sure that that is what we have in mind in supporting the model of a research agency like the Health Effects Institute. That is the reason for supporting. That is that we do believe that methodologies, generic methodologies, can be developed from the standing nature of risks, not things related to establishing giving each product a seal of approval. That's not what we're talking about. We're not talking about testing each thing in isolation. We're talking about developing generic methodologies; that is, things which can be useful for a better understanding of the whole question. I believe that's quite possible.

Mr. Ritter. Now someone, an individual will testify later saying that no science of risk assessment has been developed, and also that the question of liability insurance has not been settled. And until both these questions are answered, we should not go ahead with the release of "live, genetically engineered organisms into the open environment."

What is your comment on that?

Dr. SCHAECHTER. I think that there is at least something to be said for common sense in the absence of well-developed theories and well-developed fields of study like risk assessment.

There is a great deal of common sense that says there are some things you can do where the benefit is visible, the benefit is worth it, and the risk is minimal. I don't think that one needs to have a science called risk assessment to say it's OK for me to cross the street. I mean, we don't take our chances when we get out of bed in the morning based on a theory; we do it on the basis of experience and common sense. I would not like to discard those as major tools that human beings can handle.

Mr. RITTER. I wouldn't mind sleeping a little later. [Laughter.]

This job doesn't permit it.

Mr. Chairman, thank you. I yield back.

Mr. VALENTINE [acting chairman]. Mr. Henry.

Mr. HENRY. No questions.

Mr. VALENTINE. Does any other member of the subcommittee have any questions?

[No response.]

Mr. VALENTINE. If not, thank you very much, lady and gentleman.

The next panel consists of Mr. Richard Godown, executive director of the Industrial Biotechnology Association with Dr. Alan Goldhammer.

You gentlemen will—the prepared statements that you have will be a part of the record, of course, and you're free to summarize or proceed in any way that you deem appropriate.

STATEMENT OF RICHARD GODOWN, EXECUTIVE DIRECTOR, INDUSTRIAL BIOTECHNOLOGY ASSOCIATION; ACCOMPANIED BY DR. ALAN GOLDHAMMER

Mr. GODOWN. Thank you, Mr. Chairman.

I am Richard Godown, the executive director of the Industrial Biotechnology Association, and I am accompanied by Dr. Goldhammer who is a biochemist and who also happens to be the director for technical affairs for IBA, and who will be joining me in responding to questions from the panel.

We will summarize our remarks this way: We want to thank you for giving IBA the opportunity to present our views on H.R. 4452, an omnibus bill designed to address regulatory and scientific issues concerned with genetically engineered organisms. The speed with which the recombinant DNA and cell fusion or hybridoma technologies have been transferred to the commercial sector is remarkable.

The perception has arisen that some biotechnology products, however, are not adequately regulated by Federal agencies. Specific concerns have been sparked by procedural problems surrounding the approval for field experiments of genetically engineered organisms. These questions arose at the time when regulatory agencies were in the final process of formulating policy. It was outlined in the Federal Register back in December 1984.

In that statement the Office of Science and Technology Policy assessed the Federal statutes applicable to the regulation of biotechnology and concluded that no new legislative initiatives were needed. IBA continues to support this view.

We also believe that product-specific review of new developments within the framework of existing authorities is desirable and has worked in the past. This is consistent with the view of FDA, the agency with the most experience in biotechnology product review.

Unreasonable regulation can stifle innovation and hinder the ability of the U.S. firms to compete in what has already become a world economy.

Turning now to title I of the bill, Biotechnology Science Coordinating Committee, IBA does not see the need for legislation to establish another BSCC. The use of the Federal Coordinating Council for Science, Engineering, and Technology as a mechanism for creating the BSCC appears to have accomplished the goals established in this bill and has an added advantage of not requiring legislative dissolution if and when it's no longer needed.

One area of concern to IBA member companies is that this bill may permit nongovernmental persons to participate in BSCC deliberations. This raises the issue of whether any confidential business information that the committee may see is adequately protected.

Going now to title II of the bill, the biotechnology science research program, the goal of any regulatory program developed for biotechnology products should be to conduct a benefit-risk analysis based on sound, scientific evidence. Most products are best reviewed on a case-by-case basis unless—I'm sorry—until we have developed enough scientific expertise for a generic approach to regulation.

One section of this proposal that troubles IBA is a restriction on Federal funds for the program. The BSRP is to be funded by both the private sector and the Government with the Federal contribution not exceeding half the funding. IBA would point out that many of the companies engaged in research and development projects are entrepreneurial and formed within the past 10 years; that is, biotechnology companies.

Given their limited resources, it is difficult to see how they can contribute significant amounts of money to such a program. Larger companies with biotechnology ventures will also be reluctant to underwrite this program because product reviews are not yet accruing.

If the degree of funding of BSRP is limited because of constraints on industrial R&D allocations or Federal funds as a result of Gramm-Rudman, it becomes imperative to select those projects that are critical toward meeting near-term agency requirements. It is not certain that without greater involvement by either the regulated industry or the agencies that this will occur. Industry may have different perspectives on what research may be required, and some mechanism for conveying this should be incorporated into the proposed plan.

Setting of research priorities requires participation from all the respective parties—that is, industry, the agencies, and the public sector.

We go now to title III. IBA's comments to EPA last year regarding the agency's proposed regulation of biotechnology under the Toxic Substances Control Act or TOSCA—in those comments we agreed that the statute was appropriate for the regulation of certain biotechnology products. As the subcommittees are aware, EPA has given considerable thought as to how TOSCA can be used to regulate applications of biotechnology. We would caution against a new approach when there is no proof that the present premanufacturing notice process will not work.

Rather than modifying the act, IBA believes that EPA should be given the authority to utilize the statute as structured. The agency has ample authority under section V to require an adequate risk assessment of the genetically engineered microorganisms and can use section VIII to require reporting of adverse effects from those microorganisms already in commerce.

H.R. 4452 unfairly singles out, we think, one aspect of biotechnology, and that is intergeneric gene engineering for special regulation. IBA does not believe that this class of genetic manipulation presents any greater degree of risk compared to other generic manipulations. Product-oriented regulation based on scientifically based risk assessment will identify those products that warrant special concern regardless of the technology used in manufacture. We do not believe that anything is gained by changing TOSCA from a notification to a permitting statute for this class of biotechnology products.

We turn now to title IV of the bill and USDA regulation. As in the previous section, this title would set up a permitting system for the review of certain classes of genetic manipulations that are regulated by the USDA. IBA has concerns about this approach similar to those which we've discussed with regard to title III.

We believe that reviews of products, whether at the precommercial or commercial stage, should be carried out by that section of the agency given statutory authority to conduct reviews. In the case of USDA, we believe that this group is the Animal and Plant Health Inspection Service or APHIS. The wording of title IV does not discuss under what section the agency—what section of the agency these permitting reviews are to take place or if, in fact, a separate section is to be formed. Also, no provisions are in this section regarding the protection of confidential business information, a key factor if early R&D projects are to be subjected to agency review. We would point out that APHIS has such procedures and that they are adequate to meet industry's needs.

This bill stresses the negative potential for commercial biotechnology and does not give credence to the centuries of experience with beneficial applications of the manipulation of genetic material in agriculture, in animal husbandry, and domestic and large-scale waste treatment, and in fermentation. No commentator has provided examples of substantial harm that has arisen from these commercial applications of what we call traditional biotechnology.

With the tools that the new biotechnology provides, scientists can now precisely direct and evaluate generic transformations and thus significantly reduce the potential for the development of organisms with undesired traits.

One concern that IBA has is that a bureaucracy, once created, tends to perpetuate itself and thus, unless Congress provides for a critical assessment of the need for the permit system included in this bill, a new bureaucracy will be created which we believe will act as a break upon the commercialization of this important technology.

Mr. Chairman, I'd like, if I may, to address just a paragraph or two of formal comments also to questions which were directed to us in the letter of invitation.

Mr. VALENTINE. All right. We're going to have to break to go vote. We can finish. How long will it take? Finish with you maybe——

Mr. GODOWN. Two minutes.

Mr. VALENTINE. Two minutes. Shoot.

Mr. GODOWN. I'd like to address a few words to the interrelated subjects of risk and insurance. Risk per se—that is, identification of hazards and assessment of consequences—has been with biotechnology from the beginning when a voluntary moratorium on all laboratory experiments was agreed to by scientists responsible for the development of recombinant DNA technology. Guidelines were then promulgated by the NIH Recombinant DNA Advisory Committee to deal with unpredictable dangers. The historical record of the actions has shown that the dangers feared were dramatically overstated and that the NIH guidelines have been relaxed to reflect that very fact.

Many of the scientists involved in the call for the moratorium now recognize the consequences of their hasty action; that is, the development of a valuable research tool as well as a technology useful for the production of products with distinct societal benefits was slowed.

The conclusion is that the recombinant DNA technology is not a priori any more hazardous than traditional genetic manipulation technologies of which there is a long history of safe and beneficial use.

A further conclusion is that moving forward with caution while applying the laws of scientific probability afforded protection for both man and the environment.

In a similar vein, the Council on Environmental Quality through its regulations instructs Government agencies that in reviewing environmental impact statements to evaluate reasonably foreseeable, significant adverse effects on the human environment, the term "reasonably foreseeable" shall be taken to include impacts which have catastrophic consequences even if their probability of occurrence is low, provided that the analysis of the impact is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason—again, a standard of probability and not mere possibility.

Shifting now to a petition filed with the Environmental Protection Agency, we note that that agency has been requested to adopt immediately an interim policy requiring evidence of financial responsibility applicable to all pending applications for experimental use permits. The fact that there is no statutory basis on which the agency could possibly base such action, we will simply put down to oversight.

Mr. VALENTINE. That's the longest 2 minutes I've ever seen. [Laughter.]

That's a congressional 2 minutes. We're going to have to go. Don't go away.

Mr. Godown. All right. [Laughter.]

[Recess taken.]

Mr. Valentine. Mr. Godown, did you finish?

Mr. Godown. Mr. Chairman, if I can have 1 more of those valuable 2 minutes, sir.

Mr. Valentine. Well, we understand. I didn't mean that by any stretch of the imagination to be critical because we understand these long—that was just a long congressional 2 minutes. That's OK.

Mr. Godown. Yes, sir. Thank you.

Just to recoup for a moment, I had made illusion to the fact that the Environmental Protection Agency had been requested by petition to adopt immediately an interim policy requiring evidence of financial responsibility—by that we mean insurance—applicable to all pending applications for experimental use permits. That would include the permits in California for Dr. Lindow.

The fact that there is no statutory cases on which the Agency could possibly base such action we would put down to an oversight. The importance for us here today is the fact that in attempting to establish a rationale for this request, petitioners state that—and I quote—"An ecological and/or public health disaster from the release of a recombinant microorganism that causes harm could be of even greater magnitude than that resulting from a meltdown and, unlike a meltdown, it could continue indefinitely."

It is possible to conceive of this doomsday scenario, but on the basis of known facts and scientifically based probabilities, is it likely? The record established in biotechnology through experiment, research, and developments suggest emphatically it is not. To construct an insurance requirement for an entire regulatory system on the basis of pure conjecture or unreasonable fear, rather than on scientifically based probabilities, could throttle an extremely important industry still in its early stage. We know that this is not the intent of Congress.

Mr. Chairman, thank you very much.

[The prepared statement of Mr. Godown follows:]

TESTIMONY OF THE INDUSTRIAL BIOTECHNOLOGY ASSOCIATION
BEFORE THE SUBCOMMITTEES ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT;
AND SCIENCE, RESEARCH AND TECHNOLOGY
OF THE COMMITTEE ON SCIENCE AND TECHNOLOGY
HOUSE OF REPRESENTATIVES

JUNE 5, 1986

Mr. Chairman thank you for giving IBA the opportunity to present our views on H.R. 4452, an omnibus bill designed to address regulatory and scientific issues concerned with genetically engineered organisms. The speed with which the recombinant DNA and cell fusion or hybridoma technologies have been transferred to the commercial sector is remarkable. In a little over 10 years, these research tools have spawned a new industry whose impact on society is now being felt. Two therapeutic human proteins produced by rDNA and a number of medical diagnostics for human health care have been introduced with the approval of the Food and Drug Administration (FDA). With over a dozen biotechnology products in various stages of clinical testing, it is evident that the societal benefits from this new technology will significantly increase in the future.

Amidst these positive developments, the perception has arisen that some biotechnology products are not adequately regulated by federal agencies. Specific concerns have been sparked by procedural problems surrounding the approvals for field experiments of genetically engineered organisms. These questions arose at a time when regulatory agencies were in the final process of formulating policy that was outlined in the _Federal Register_ in December of 1984. In that statement (49 _FR_ 50858), the Office of Science and Technology Policy (OSTP) assessed the federal statutes applicable to the regulation of biotechnology and concluded that no new legislative initiatives were needed. IBA continues to support this view. The majority of products using the new technologies will not be substantially different from existing products which have been regulated under present statutory authority.

IBA believes that product-specific review of new developments within the framework of existing authorities is desirable and has worked in the past. This is consistent with the view of the FDA, the agency with the most experience in biotechnology product review. Unreasonable regulation can stifle innovation and hinder the ability of United States firms to compete in what has become a world economy.

Because the bill being considered today contains a number of different proposals, both regulatory and non-regulatory, IBA believes that it is important to discuss them all. The following sections of this testimony present the Association's views on the four titles that comprise H.R. 4452.

Title I--Biotechnology Science Coordinating Committee

The formation of the Biotechnology Science Coordinating Committee (BSCC) arose out of a proposal from OSTP in December 1984 (49 FR 50904). IBA commented to OSTP in response that there is a need to coordinate federal efforts in both the risk management and regulatory areas. It is important that regulatory decisions are based upon the best available scientific information and are consistent not only with respect to products submitted for review to one agency but between agencies as well. In so far as the BSCC can accomplish this task it should be encouraged.

IBA does not see the need for legislation to establish another BSCC. The use of the Federal Coordinating Council for Science, Engineering and Technology as a mechanism for creating the BSCC (50 FR 47174) appears to have accomplished the goals established in this bill and has an added advantage of not requiring legislative dissolution if it is no longer required.

Using the NIH experience as an example, the Guidelines for Recombinant DNA Research, initially quite stringent, have been relaxed over time so that most laboratory and research experiments do not require NIH review. It is IBA's expectation that, as regulatory agencies gather experience with genetically engineered products, the need for the BSCC will diminish as time goes by. However, if the Congress decides to create the BSCC by law, this should be accompanied by a "sunset clause" that would provide the opportunity to evaluate its need at an appropriate time interval.

One area of concern to IBA member companies is that this bill may permit non-governmental persons to participate in BSCC deliberations (Sec. 103 (5)). This raises the issue of whether any confidential business information that the committee may see is adequately protected. In view of the highly competitive nature of the new technology, IBA believes that strong trade secret protection is needed.

Title II--Biotechnology Science Research Program (BSRP)

The goal of any regulatory program developed for biotechnology products should be to conduct a benefit-risk analysis based upon sound scientific evidence. This may require the development of additional scientific expertise in those areas where there is demonstrated lack of information. This will not preclude the evaluations of biotechnology products by regulatory agencies, but will rather contribute towards the formulation of generic test guidelines. At present, most products are best reviewed on a case-by-case basis until we have developed enough scientific expertise for a generic approach to regulation.

For some applications of biotechnology, however, we have reached the point where generic approaches to risk assessment can be considered. This would be the use of genetically engineered organisms in contained fermentation facilities for the production of metabolic products such as amino acids, enzymes, antibiotics, and proteins for therapeutic use. Assessments of workplace and environmental exposure have been done based upon the organism, containment of the fermentation process, and the nature of the product being produced.

However, the increasing emphasis upon the use of live genetically engineered organisms in the environment has raised new questions. Questions about survival and persistence in the environment, dispersal, and transfer of genetic information have been identified as areas needing further research.

The BSRP presents an interesting approach towards addressing research needs. At present research directed at developing information for risk assessment occurs at different agencies throughout the government. Research conducted by EPA is directed at specific issues while funding agencies such as NIH and NSF are not directed towards answering specific regulatory questions. It appears that the BSRP, through its interaction with the BSCC, will be able to better focus the research pertaining to regulatory needs.

One section of this proposal that troubles IBA is the restriction on federal funds for the program (Section 202 (c)(1)(a)). The BSRP is to be funded by both the private sector and the government with the federal contribution not exceeding half of the funding. IBA would point out that many of the companies engaged in research and development projects are entrepreneurial and formed within the past 10 years. Given their limited resources, it is difficult to see how they can contribute significant amounts of money to such a program. Larger companies with biotechnology ventures will also be reluctant to underwrite this program because product revenues are not yet accruing.

If the degree of funding of BSRP is limited because of constraints on industrial R&D allocations or federal funds as a result of Gramm-Rudman it becomes imperative to select those projects that are critical towards meeting near term agency requirements. It is not certain that without greater involvement by either the regulated industry or the agencies that this will occur. Industry may have different perspective on what research may be required and some mechanism for conveying this should be incorporated into the proposed plan. Setting of research priorities requires participation from all of the respective parties: industry, the agencies, and the public sector.

Title III--EPA Regulation

IBA believes the regulation of biotechnology should be product-driven rather than technology-driven. Singling out specific technologies for increased or special oversight implies that there are *a priori* unique hazards associated with products of that technology. This is neither a prudent regulatory approach nor one that will encourage the development of innovative technologies.

IBA believes that because of the recent focus on the regulation of recombinant DNA research and its products, that the historical record of the industrial applications of genetically manipulated microorganisms has been obscured. The societal benefits derived from improved processes for the production of antibiotics, high fructose corn syrup, or microbial-enhanced pollution control would not be possible without the deliberate manipulation of microorganisms.

In IBA's comments to EPA last year regarding the Agency's proposed regulation of biotechnology under the Toxic Substances Control Act (TSCA), we agreed that the statute was appropriate for the regulation of certain biotechnology products. TSCA was designed as a gap-filling statute, to regulate those materials not subject to regulation by other agencies or statutes. Manufacturers of "new" chemical substances must notify EPA prior to manufacture for commercial purposes. EPA can, after an assessment of the substance, regulate the manufacture of those chemical substances and mixtures which present an unreasonable risk of injury to health or the environment. The statute makes use of an Inventory listing of chemical substances; substances not listed on the Inventory are considered to be "new" and require the submission of a premanufacture notification (PMN) under Section 5 of the Act. We would note that many microorganisms and microbial products are already listed on the TSCA Inventory.

As the subcommittee is aware, EPA has given considerable thought as to how TSCA can be used to regulate applications of biotechnology. We would caution against a new approach when there is no proof that the present PMN process will not work. Rather than modifying the act, IBA believes that EPA should be given the opportunity to utilize the statute as structured. The Agency has ample authority under Section 5 to require an adequate risk assessment of the genetically engineered microorganism and can use Section 8 to require reporting of adverse effects from those microorganisms already in commerce.

H.R. 4452 unfairly singles out one aspect of biotechnology, inter-generic gene engineering, for special regulation. IBA does not believe that this class of genetic manipulation presents any greater degree of risk compared to other genetic manipulations. Product-oriented regulation based on scientific-based risk assessment will identify those products that warrant special concern, regardless of the technology used in manufacture. We do not believe that anything is gained by changing TSCA from a notification to a permitting statute for this class of biotechnology products.

IBA has the following specific comments on various parts of this section of the bill:

Section 32 (b): EPA has acknowledged that other agencies have more expertise about the use of plants or animals either as whole organisms or _in vitro_ cultures (49 _FR_ 50887). IBA concurs and these applications should not be subject to TSCA.

Section 32 (c)(2)(A): Workplace exposure and training issues are covered by the Occupational Safety and Health Act.

Section 32 (d): Any company engaging in experimental manufacturing for research and development will be required to obtain a permit. This would appear to regulate _any_ fermentation of a genetically engineered organism as defined by Sec. 32 (b) prior to commercial introduction. This is inconsistent with other regulatory statutes and ignores the NIH experience.

Section 32 (d)(9)(A): The nature of the information a company would be required to pass along to the public and local officials is not specified. IBA is extremely concerned that this requirement could involve the dissemination of trade secrets.

Section 32 (f)(2): While the bill makes provisions for waiving an expanded use permit, no provision is made for waiving an initial use permit for those cases that warrant it.

Section 32 (h): It is not clear whether the Biotechnology Advisory Panel is supposed to be an internal committee of EPA scientists or composed of external scientists.

Title IV--USDA Regulation

As in the previous section, this title would set up a permitting system for the review of certain classes of genetic manipulations that are regulated by the USDA. IBA has concerns about this approach similar to those discussed above.

In addition, the language of this section raises a number of uncertainties as far as we are concerned. IBA believes that reviews of products, whether at the pre-commercial or commercial stage, should be carried out by that section of the agency given statutory authority to conduct reviews. In the case of the USDA, we believe that this group is the Animal and Plant Health Inspection Service (APHIS). The wording of Title IV does not discuss under what section of the Agency these permitting reviews are to take place or if in fact a separate section is to be formed.

No provisions are in this section regarding the protection of confidential business information, a key factor if early R&D projects are to be subjected to agency review. We would point out that APHIS has such procedures and they are adequate to meet industry's needs.

Subsection (h) establishes an Agricultural Recombinant DNA Advisory committee composed of individuals from the Department's research and regulatory divisions. No provisions are present for convening a panel of outside experts which may be needed for certain product reviews. EPA's Office of Pesticide Products has used their external Science Advisor Panel for such uses. IBA believes that it is important to get the best scientific expertise involved in the review process regardless of whether such individuals are in the agency or the university system.

This bill stresses the negative potential for commercial biotechnology and does not give credence to the centuries of experience with beneficial applications of the manipulation of genetic material in:

Agriculture
Animal Husbandry
Domestic and large scale waste treatment
Fermentation.

No commentator has provided examples of substantial harm that has arisen from these commercial applications of what we call "traditional biotechnology." With the tools that the "new biotechnology" provides, scientists can now precisely direct and evaluate genetic transformations, thus, significantly reducing the potential for the development of organisms with undesired traits. In view of this we would urge that the bill be modified to:

1. Provide for sunset of the permit provisions after five years unless Congress determines adequate reason exists for extending such requirements.

2. Require EPA and USDA to report to Congress within four years of the effective date on the respective agency's experience with the regulation of biotechnology and with their recommendations for what, if any, changes in procedure or jurisdiction would be appropriate to protect public health and the environment.

3. Require that the Department of Commerce and the Department of State report to Congress on the development of this fledgling industry, both domestically and abroad and also report to Congress on the domestic and international trade aspects of the commercialization of biotechnology.

One concern that IBA has is that a bureaucracy once created tends to perpetuate itself and, thus, unless Congress provides for a critical assessment of the need for the burdensome permit system included in this bill, a new bureaucracy will be created which we believe will act as a brake upon the commercialization of this important technology.

In addition, we believe that the bill should provide for a study of ways in which this new industry can be helped to compete with efforts that are being undertaken abroad. We thank you for this invitation to express our views before the Subcommittees.

Mr. Chairman, I would like to address a few words to the interrelated subjects of risk and insurance.

Risk per se, i.e. identification of hazards and assessment of consequences has been with biotechnology from the beginning, when a voluntary moratorium on all laboratory experiments was agreed to by scientists responsible for the development of recombinant DNA technology. Guidelines were then promulgated by the NIH Recombinant DNA Advisory Committee to deal with unpredictable dangers. The historical record of these actions has shown that the dangers feared were dramatically overstated and the NIH Guidelines have been relaxed to reflect that very fact. Many of the scientists involved in the call for the moratorium now recognize the consequences of their hasty action, i.e., the development of a valuable research tool as well as a technology useful for the production of products with distinct societal benefits was slowed. The conclusion is that recombinant DNA technology is not a priori any more hazardous than traditional genetic manipulation technologies of which there is a long history of safe and beneficial use. A further conclusion is that moving forward with caution while applying the laws of scientific probability afforded protection for both man and the environment.

In a similar vein, the Council on Environmental Quality thru its regulations instructs government agencies that, in reviewing environmental impact statements to evaluate reasonably foreseeable significant adverse effects on the human environment, the term "reasonably foreseeable" shall be taken to include "impacts which have catastrophic consequences, even if their probability of occurence is low, provided that the analysis of the impacts is supported by credible scientific evidence, is not based on pure conjecture and is within the rule of reason". Again, a standard of probability, not mere possibility.

Shifting now to a petition filed with the Environmental Protection Agency by the Foundation on Economic Trends, we note the Agency has been requested to adopt immediately an interim policy requiring evidence of financial responsibility applicable to all pending applications for Experimental Use Permits. The fact that there is no statutory basis on which the Agency could possibly base such action we will simply put down to an oversight or perhaps careless draftsmanship. The importance for us here today is the fact that in attempting to establish a rationale for their request, petitioners state that "An ecological and/or public health disaster from the release of a recombinant microorganism that causes harm could be of even greater magnitude than that resulting from a meltdown -- and unlike a meltdown it could continue indefinitely". It is possible to conceive of this doomsday scenario but on the basis of known facts and scientifically based probabilities, is it likely? The record established in biotechnology thru experiment, research and development suggests emphatically, it is not. To construct an insurance requirement or an entire regulatory system on the basis of pure conjecture, or unreasonable fear, rather than on scientifically based probabilities could throttle an extremely important industry still in its early stage. We know that is not the intent of Congress.

Mr. VALENTINE. Thank you, sir.

Doctor.

Dr. GOLDHAMMER. I'm available to answer any questions should the chairman require it.

Mr. VALENTINE. Let me ask you this question: Under FIFRA there's a requirement that—a requirement for submission of data to the agency to justify granting a permit when an organism is to be used, say, as a pesticide. Under TSCA it's sufficient for the company simply to notify the Agency, as I understand it, that it's producing a product such as an organism to be used in a hazardous waste cleanup.

Since EPA is charged with protecting the environment, doesn't it seem reasonable to have the same degree of perspective scientific review with organisms intended for use in the environment under both FIFRA and TSCA?

Mr. GODOWN. Well, let me respond this way, Mr. Chairman: I think the question presumes that the same kind of review is not given, and I'm not sure that that's the fact. TSCA is a prenotification—has a prenotification requirement, and also a premanufacturing notice requirement. And there is ample opportunity for the Agency, for EPA, to review and there is also regulatory authority for EPA to halt the progress of a product into the stream of commerce if it sees fit.

Mr. VALENTINE. What is now the burden of proof? Does some presumption arise? Do you allow the project to proceed or does some showing have to occur at the beginning and, if so, for which side?

Mr. GODOWN. May I ask my scientific expert?

Dr. GOLDHAMMER. Yes. It falls under section 5 of TSCA, and EPA, the Administrator of EPA can use section 5(e) to make a finding that there will be some result of harm to the environment and the agency can take action.

If you're considering the absolute burden of proof, TSCA is different from FIFRA in that the burden of proof is placed upon the regulatory agency in this case as opposed to under the pesticides statute where the burden of proof is on the manufacturer.

Mr. VALENTINE. Do the various Federal agencies at the present time have clear authority to review all genetically engineered organisms which are intended for environmental release in both research and commercial settings?

Mr. GODOWN. I would answer this way: we think that the statutory basis for doing so is there and it is certainly possible that the regulation's extent or additional regulations under consideration may be necessary in order to make the matter clearer.

Also, we will all know a great deal more when we see these guidelines which have been discussed here today.

Mr. VALENTINE. Congresswoman Schneider.

Miss SCHNEIDER. On that note, someone just mentioned to me that you had copies of the guidelines. Is that not true?

Mr. GODOWN. I do not have copies of the guidelines.

Miss SCHNEIDER. You haven't seen them?

Mr. GODOWN. Nope.

Miss Schneider. Well, OK. I'm curious to know about how your industry feels about dealing with two separate agencies on a variety of these questions.

Mr. Godown. I think as long as the guidelines are clear about who's doing what to whom, it certainly isn't objectionable. The point needs to be made that in many instances one agency will ask another or a variety of other agencies to help them in the review process, and in that instance, of course, you have to satisfy the demands of more than one agency. So as long as there is coordination, we don't see it particularly as a stumbling block.

Miss Schneider. Which doesn't exist right now? Lots of room for improvement you're suggesting?

Mr. Godown. Yes, Ma'am.

Miss Schneider. OK. I'm sorry, I came in just as you were finishing your answer to Congressman Valentine having to do with the TSCA implications. Did you mention anything about the General Accounting Office's criticism of the current regulatory scheme that EPA has been using in implementing TSCA?

[Mr. Godown shakes head negatively.]

Miss Schneider. No? Are you aware that the GAO has been very critical of EPA's implementation?

Mr. Godown. Has been very critical of USDA's implementation?

Miss Schneider. EPA's, the Environmental Protection Agency's.

Mr. Godown. I have not seen that.

Miss Schneider. Are you of the opinion that TSCA is working well?

Dr. Goldhammer. With respect to biotechnology or the chemical industry?

Miss Schneider. No, no, biotechnology——

Dr. Goldhammer. Well, the——

Miss Schneider [continuing]. The regulatory structure. Do you think it's——

Dr. Goldhammer. We haven't yet seen any applications that would be subject to TSCA in the environmental release area. If you're considering the particular products that we expect to be possibly near-term applications, I think one would be in the pollution control area. Most of these are still in the laboratory stage. It's not projected, to my knowledge, that people are going to be ready to go out in the field for at least another year, maybe 18 months, with only relatively a small number, less than six probably, genetically engineered micro-organisms here.

Given that, we think that EPA, when we've all seen their proposal, I think we can assess its adequacy.

Miss Schneider. OK. Are you familiar with the efforts of removing the sulphur from high sulphur coal through a biogenetic-engineered organism?

Dr. Goldhammer. I have read reports that there are some people that have developed organisms. The reports that I have read—that these are organisms that are already found in nature and have not been genetically—specifically genetically engineered, and, therefore, I would assume wouldn't present much of a regulatory problem.

Miss Schneider. I see. Are you familiar with how other nations are regulating their biogenetic engineering?

Dr. GOLDHAMMER. Yes. There has been report, and I believe it was released—or I heard from the Executive Office was released last week—that was compiled under the auspices of the Organization for Economic Cooperation and Development—I got it out—OECD. In this was a report that was developed by participation of all of the OECD member countries, which are Western Europe, Australia, Japan, New Zealand, and presented more or less a summary of what the regulatory policies are as well as making some recommendations as to what a baseline regulatory policy might be toward these new aspects of biotechnology.

Miss SCHNEIDER. Well, I'm inclined to ask a question whether or not you saw a similarity between what they were recommending and what our Government is recommending. But seeing as how we don't have those specifics as yet, I have no further questions, Mr. Chairman.

Mr. VALENTINE. Mr. Volkmer.

Mr. VOLKMER. Yes, I have several questions. I just want to make something real clear.

Mr. Godown, I believe in answer to the gentlelady from Rhode Island you said that you had never seen or read or been given a copy of the preamble and the guidelines that are now before the Council for approval?

Mr. GODOWN. I didn't say all of that, but I'd be willing to; yes, sir. I have not seen them.

Mr. VOLKMER. You've never had a copy of them?

Mr. GODOWN. I have not had a copy of the complete guidelines; no, sir.

Mr. VOLKMER. Have you had a copy of any of the guidelines?

Mr. GODOWN. I have seen an earlier version. I have no idea about what the final version that's being worked on by the Domestic Council is.

Mr. VOLKMER. Where did you receive the earlier version? Or from whom?

Dr. GOLDHAMMER. We received—this is not—as Mr. Godown stated, this is not a compendium of complete guidelines. The only thing that we have seen in our office is a copy of a very early draft of the EPA policy proposal. We have not seen the USDA proposal, the FDA proposal, nor have we seen the preamble.

Mr. VOLKMER. All right. Where did you receive the copy of the EPA proposed guidelines?

Dr. GOLDHAMMER. It arrived in the mail in a brown paper envelope. [Laughter.]

Mr. VOLKMER. No return address. Did it have a postmark on it? [Laughter.]

Or did it have any postage on it at all?

Dr. GOLDHAMMER. I assume—it must have had postage on it because it did come by the U.S. Postal Service.

Mr. VOLKMER. It wasn't franked, was it? [Laughter.]

Dr. GOLDHAMMER. It did not have a congressional frank on it.

Mr. VOLKMER. All right.

Mr. GODOWN. May the record show that I did not see the envelope. [Laughter.]

Mr. VOLKMER. Mr. Godown, then I have another question.

Mr. GODOWN. Yes, sir.

Mr. VOLKMER. Were you given the opportunity to review Mr. Johnson's testimony before today?

Dr. GOLDHAMMER. We exchanged testimony with OSTP. We did not offer any comments to one another as to what should be said by either group.

Mr. VOLKMER. So you were furnished a copy of his testimony last week?

Dr. GOLDHAMMER. It was a draft copy, not what—in fact, what he testified on today was quite different from what we received last week.

Mr. VOLKMER. Was that solicited or nonsolicited?

Dr. GOLDHAMMER. That was nonsolicited.

Mr. VOLKMER. Without even your asking for it?

Dr. GOLDHAMMER. Yes; I did not request it.

Mr. VOLKMER. Mr. Chairman, the reason for that question is that we attempted to get Dr. Johnson's testimony in advance last week and we were refused a copy. I just thought it would be noteworthy for the record.

Miss SCHNEIDER. Mr. Chairman, I have another question.

Mr. VALENTINE. Yes. Are you finished?

Mr. VOLKMER. No; I'm not finished. I will yield to the gentlelady, though, for the time.

Miss SCHNEIDER. It is not related to the line of questioning that you are pursuing, however, so if you want to continue——

Mr. VOLKMER. Go ahead. Go ahead. I'm not going to pursue it any further.

Miss SCHNEIDER. I thought that we were about to conclude, and another question occurred to me having to do with your trade association.

I was wondering, To what degree, if any, has your association come up with some specific guidelines for operating principles on your own rather—or have you done such a thing as an industry?

Mr. GODOWN. Guidelines pertaining to?

Miss SCHNEIDER. Self-regulation or self-monitoring of both research and release dealing with genetically engineered organisms.

Mr. GODOWN. I think the proper response is that—well, certainly the factual response is that, no; there are no IBA guidelines which go along those lines or speak to that question, but certainly there are within the industry a great number of scientists and other professionals, all of whom have ethical principles and adhere to those ethical principles of their profession, and we are very, very pleased with the general conduct of people within the industry, if I may say so for the record.

I think going back to the voluntary moratorium in the beginning when there was some question about the impact of recombinant DNA indicates the attitude toward both the scientific and the business contingent of this new industry.

Miss SCHNEIDER. I will agree with you on that point. It does concern me, however, as we're moving into an advanced realm of activity here, however, that self-regulation and voluntary restraint certainly has a role, but I would think that when you were looking at the Federal guidelines or Federal proposals which we'll eventually see, I would think you would already have some positions that would be more specific as opposed to saying, "Well, we don't think that there should be any legislation such as being proposed today by Mr. Fuqua." Rather than an extreme position of all or nothing, I would think you would have some specific guidelines that as a trade association you would have come up with.

Mr. GODOWN. Let me say simply that it is not an unconsidered position that we take here today. We've examined Chairman Fuqua's bill with great particularity, and we have fanned it out to a variety of committees within our own organization, and we are reflecting here not only our own insights and intelligence on the matter, but we are reflecting the attitudes of the industry.

No. 2, on the question of guidelines, I will say for the record that we are currently in the process of formulating ethical guidelines for the biotechnology industry which we anticipate will be adopted by our board of directors and will then be adhered to of necessity by those people who belong to the organization now and those who become our members hereafter.

Miss SCHNEIDER. Well, that is specifically what I was asking.

Mr. GODOWN. Yes.

Miss SCHNEIDER. And I do think that it is probably a very good idea that you're doing that, lest your whole association suffer because of the actions of perhaps one industry.

Mr. GODOWN. Quite so.

Dr. GOLDHAMMER. If I could just add two things to that—in a survey that I did about 18 months ago when I think a similar question arose, I looked and contacted NIH to find out how many people voluntarily had registered with the recombinant DNA office there, of their own institutional biosafety committees. And all—at that time—this was 18 months ago—all of the IBA member companies had voluntarily registered with NIH.

And, as a second point here, we did comment rather extensively to OSTP in their request for comments on the regulation, and I think that we did provide them at least with our thoughts for how reasonable framework could operate, and we would be glad to make those available to you.

Miss SCHNEIDER. Good. Thank you.

Mr. VALENTINE. Thank you.

Mr. Volkmer, do you have any further questions?

Mr. VOLKMER. Yes; I do. I would like to continue on with a few in regard to TSCA, which we haven't had any genetically engineered product that—application for licensing yet.

But correct me if I'm wrong. If I give an example, tell me if I'm wrong or not. Under present TSCA regulation and law, that if I was a company that developed a—even using a pathogenic microbial product, that I could test it on—I don't remember the minimum, but there's a minimum quantity of water—and if the results satisfied what I thought would be a positive result as far as EPA's concerned, I would then forward it on, the data on to EPA for purpose of licensing; correct so far?

Dr. GOLDHAMMER. Yes. Your assessment is correct, and I think in anticipating your question, we have long recognized that there is a potential problem between the jurisdiction under FIFRA and that under TSCA, and that TSCA does permit unlimited research and development activities to take place in the commercial sector.

In our comments to OSTP that I just alluded to in response to Congresswoman Schneider, we at the association have taken the position that this needs to be rectified; that research and development activities of TSCA related microbial products need to be looked at on an interim basis by the regulatory agency until we've got enough information to go back to what traditional R&D exemption has stood for.

Mr. VOLKMER. Basically you would agree, then, that prior to any release into the environment of any of these products that the previous panel discussed, whether it's intergeneric or whether it's pathogenic, that even under TSCA those things would be defined basically as chemicals—should meet an approval by EPA before they're even field tested?

Dr. GOLDHAMMER. Yes; we do.

Mr. VOLKMER. And any research done on them should be done in a controlled laboratory or controlled area, et cetera?

Dr. GOLDHAMMER. Yes; we do.

Mr. VOLKMER. All right. Then basically you agree that we should follow the same guidelines as far as any chemical or any type of product, biotechnical product, developed in genetic engineering under TSCA as we do under FIFRA?

Dr. GOLDHAMMER. Yes; we do.

Mr. VOLKMER. All right. Now what—well, maybe I should ask you this: Do you agree generally with the previous panel as to the types of genetically engineered products that should be regulated, those that are intergeneric, those that are pathogenic?

Dr. GOLDHAMMER. Yes; we do.

Mr. VOLKMER. Do you, then, since you also are in the USDA field, do you also agree that USDA's guidelines should follow the same structure as EPA and FIFRA?

Dr. GOLDHAMMER. We think it's only prudent that there's a consistency of regulatory policy throughout the Federal Government, and we've gone on the record with this.

Mr. VOLKMER. It would be beneficial basically, would it not?

Dr. GOLDHAMMER. Yes; it would.

Mr. VOLKMER. That you're going to basically follow the same thing whether you go to EPA or USDA?

Dr. GOLDHAMMER. Yes.

Mr. VOLKMER. Whether you do it under TSCA or FIFRA or APHIS or anything else?

Dr. GOLDHAMMER. We certainly believe that would be in the best interest of industry.

Mr. GODOWN. A most desirable goal.

Mr. VOLKMER. In our discussions, by the way—I think, coming from your side, would be very helpful to us—in our discussions with USDA in developing the use, over there, of what is now the ARRC but I think is going to change to the BARRC, or whatever it is [laughter] anyway, their scientific review council there, that one of the concerns we heard expressed from USDA officials was being able to utilize outside-USDA personnel.

In other words, independent, like EPA does in their reviews, and still maintain a propriatary information—or confidentiality of information.

Personally, it is beyond me how one can do it and the other one can't.

Can you, perhaps, help me understand why USDA cannot maintain that confidentiality and propriatary information using the same type of personnel that EPA can?

Dr. Goldhammer. We believe they can.

We raised this issue with USDA last spring when we were having discussions about the December 1984 policy statement and noted the fact in our discussion with APHIS personnel that it did not appear that they had provisions on the books at USDA for the protection of confidential business information.

They said that they were in the process of rectifying that. They did publish in the Federal Register—I believe it was early summer of last year—a proviso for the protection of confidential business information for things that were submitted to APHIS.

We did look that over; we commented back to the APHIS administrator that this appeared to be entirely appropriate to meet industry's needs.

Insofar as APHIS needs to convene expert panels, or the ARRC or BARRC or however it is going to be done, we believe that if it is done under the APHIS umbrella that the CBI provisions would hold.

We would not have any difficulty in an expert panel being constituted under that umbrella.

Mr. Volkmer. Would you have any objections with USDA basically following provisions whereby all of these products developed, whether plant or animal or whether it is a vaccine, et cetera, under the USDA proposals for animals that the, again, the agriculture review advisory committee, or the BARRC or whatever it is going to be called reviews those, as well as APHIS or the other people over there?

Dr. Goldhammer. Again, I would think that if it were consistent with what other agencies were doing for similar products we would have no difficulty with that proposal.

Mr. Volkmer. No further questions, Mr. Chairman.

Mr. Valentine. Mr. Godown, it is a fact, is it not, that noncommercial research is now totally exempt from TSCA?

[Mr. Godown defers to Dr. Goldhammer.]

Dr. Goldhammer. Yes; that is correct.

Mr. Valentine. Do not we have a real problem if industry researchers are subject to EPA but academic researchers have no supervision of a similar kind?

Dr. Goldhammer. Academic researchers would still fall under the jurisdiction of the NIH guidelines if there institution was receiving Federal funding.

Mr. Valentine. That is a kind of an "iffy" thing, but would not you have a situation where industry researchers would be subject to restriction and academic researchers would be able to release all kinds of organisms into the environment without any interference?

Dr. Goldhammer. If they are organisms constructed by recombinant DNA techniques, at present, release of those organisms into the environment is forbidden by the NIH guidelines without review by the NIH Recombinant DNA Advisory Committee and the approval of the Director of NIH.

Mr. VALENTINE. To your mind, is that quite the same as the type of regulation that one would run into with the EPA?

Dr. GOLDHAMMER. We do not know whether that is the case and, again, in our comments to OSTP last spring, we raised this issue—that there should be a comparable review of academic proposals versus commercial proposals.

We do not see any difference in risk or hazard just because it is being done at a university versus a commercial setting.

Mr. VALENTINE. But do you see any strange situation in that if it were done at one place it would not be subject to a certain type of restriction, and if it were done in another place that it would?

That is, industry as opposed to academic?

Dr. GOLDHAMMER. I think that we would, again, have to reserve our answer until we see the agency policy statements.

We could certainly comment on what NIH review looks like, but until we see what the agency is proposing—

Mr. VALENTINE. The NIH guidelines have no statutory basis, do they? They are just guidelines.

What can you do if they do not follow them?

Dr. GOLDHAMMER. They are binding.

The university could lose all of it's Federal funding.

Mr. VALENTINE. Suppose Federal funding was not involved in any way? In that rare situation?

Mr. GODOWN. Very rare. [Laughter.]

Dr. GOLDHAMMER. That, I guess, is a question that we cannot answer.

Mr. VALENTINE. Does that indicate, perhaps, the necessity for some legislation?

Dr. GOLDHAMMER. I would have to reserve an answer on that.

Mr. VALENTINE. Mr. Godown, in your testimony, as we understood it, you seemed to applaud the role of the Biotechnology Science Coordinating Committee, yet you say that you would not want that body to have any statutory authority.

Is that inconsistent?

Mr. GODOWN. I do not think so, Mr. Chairman.

Our position is precisely that; we think that the coordinating committee can accomplish some good purposes. However, if it is created to statutorily—it is kind of like building a brick wall—it is a little difficult to get it down when it is no longer needed, and it is especially difficult to modify it.

We would suggest to go ahead with the idea, but it is not necessary for a statutory basis in order to create it.

Mr. VALENTINE. Mr. Volkmer, do you have any further questions?

Mr. VOLKMER. Yes; I have a couple more.

One is something I have been thinking about and wondering, again, what the guidelines are going to propose—because I can foresee, and I would like to have your comments on this—the possibility that in the future we have a genetically engineered product that is determined to be utilized as a pesticide. Let us say it is an outgrowth of the use of a pathogenic material, but genetically engineered plant.

My question is does a person go to EPA first? And then go through the whole regulatory system and then end up with USDA later on saying, hey, this is also a toxic weed, or a bad weed, and therefore you can't release it without us looking at it—or potentially so, so we have got to look at it, too?

Dr. GOLDHAMMER. It is an interesting jurisdictional question. It is one, actually, that is fast approaching reality—that there are plants which contain insecticidal toxin genes in them.

It has not been clear to us where the jurisdiction lies. Among our member companies who are developing such products it is also—there is divided opinion as to who they would prefer going to for regulatory purposes.

Mr. VOLKMER. But did not we make sure that this is clear one way or the other, that you can follow—if you are going to have to go it two track, that you can go a simultaneous two track or you go primarily to one and the other one will be, maybe, referred to so that they can have input as to what is going on—rather than having to go through one and then go through another?

Dr. GOLDHAMMER. That certainly is preferable, yes.

Mr. VOLKMER. The reason that I brought it up was that Monsanto—and the USDA coming in lately, I think it was in May—applications coming in saying that they wanted some further tests done, and they notified EPA.

That is what gives me some concern about it, that we make sure that we don't have the problem of having one follow the other.

The last thing—does the industry envision any release of liablility in the event that there is a release to the environment, there is damage done, that has to be quote "cleaned up," or taken care of—that the mere licensing by the Federal agency would provide some relief to them for helping with the cleanup, or anything?

Or is the liability assumed to be, by the industry, solely industry's liability?

Mr. GODOWN. Answering the question as one of first impression, I would say that probably tort law is going to govern. The fact that you had a permit to go forward certainly would not keep the plaintiff's attorneys from filing suit, we know that.

How the courts would handle it is anybody's guess.

Mr. VOLKMER. My question is you do not assume, offhand, that as far as speaking for industry that industry would have the right, like the utility up at TMI wants us to help and has—we are spending taxpayers money to clean up.

You do not anticipate that your industry would come back up here and ask for tax dollars to help clean up someplace?

Mr. GODOWN. I cannot read the future, Congressman, any more than you can. I would simply, in attempt to be responsive, I would say that in the bill before us there is a provision which says that no language in the bill shall be taken to change the liability as it exists under current statutes.

I guess I would just let the answer rest there.

Mr. VOLKMER. Do you have a position at all in the IBA on the AGS' violation of FIFRA and Dr. Kit's what I would think, violation of the NIH guidelines in the question of the ice-minus and the pseudorabies vaccine field tests?

Mr. GODOWN. Addressing those one at a time, AGS is a member of IBA. That matter, that circumstance, has been addressed by our board of directors. In fact, we have been in correspondence with the company telling them as to the concern voiced by the board of directors in view of the circumstances.

With regard to the pseudorabies vaccine, that company is not a member of ours, and we have not taken a public position on that matter.

Mr. VOLKMER. Do you believe, as I do, that those type of events are a hindrance to the promotion of this type of industry, and acceptance by the public of this type of industry?

Mr. GODOWN. Again, I would divide my answer in two and say very definitely yes, in the AGS case. I think it is fairly well established, at this point, what happened there. It did not do anybody any good, including AGS, and it certainly did not do the biotechnology industry any good.

We deplore the fact that it did happen. I think the company does also, although they certainly can speak for themselves.

I am not certain, at this point, how the facts are going to turn out in the pseudorabies case. I am aware of the allegations, and I am aware of the legal action and the manuevering. But it seems to me that that is still very much open question. If it turns out that there has been wrong doing on the part of either the university or the experimenter involved, or the company involved, then of course we would view it in the same way; we would deplore that.

Mr. VOLKMER. The last thing I would like to comment on—you were here when the chairman of the full committee testified?

Mr. GODOWN. Yes, sir.

Mr. VOLKMER. I think the result of the end of the questioning period—he made a statement that what we must do is be able to assure—whatever we do, is give the confidence to the public that whatever is released out there, in this area of biotechnology, is safe to the environment and to the public.

Do you agree with that?

Mr. GODOWN. Sir, not only do I agree with it, but we would like to associate ourselves with those remarks and we are very appreciative of the fact that these two subcommittees are holding this joint hearing; and very appreciative, sir, of your own participation in it.

We think that this kind of open discussion of the difficulties and the problems and the concerns is extremely healthy. We want to continue to be responsive to whatever concerns there are. Above all, we would like to see in a reasonable, responsible manner, biotechnology proceed.

Thank you.

Mr. VOLKMER. Thank you, Mr. Chairman.

Mr. VALENTINE. Thank you, gentlemen, very much.

Mr. GODOWN. Thank you, Mr. Chairman.

Mr. VALENTINE. We are at the last witness, Mr. Jeremy Rifkin, of the Foundation on Economic Trends.

STATEMENT OF JEREMY RIFKIN, FOUNDATION ON ECONOMIC TRENDS

Mr. RIFKIN. Mr. Chairman, members of the committee, thank you for allowing me to testify here today.

Just a piece of homework first—I have been given a copy of the OSTP report, the draft report, on May 13, anonymously. I would be glad to share it with members of the committee, at your convenience, for perusal.

I would like to make a few general comments, some generic comments, and then maybe in the question and answer we can go a little bit into the White House proposal, as it stands now; although I understand it is not in its "final draft yet."

I think we have two major, generic questions involved with this whole emerging biotechnology industry, that until they are resolved make it virtually impossible to develop a regulatory mechanism that is adequate to assure safety of the public and environmental safety and health conditions.

These two pressing issues have yet to be redressed adequately by Federal agencies.

Issue one: The fact of the matter is, there is no science of predictive ecology; there is no science of risk assessment.

I have been sitting through congressional hearings and study reports for year after year after year where distinguished scientists from the environmental sciences have testified that there simply is no predictive ecology. It does not exist.

I would like to acquaint members of the committee, if you are not already aware—and indulge me, please, for a moment—with a report issued by the Environmental Protection Agency. Their advisory panel that was to look into predictive ecology issued a study in January or February of this year. I have some of the summary results of that study provided to EPA on the whole question of can we determine the risk of placing genetically engineered organisms into the environment.

You cannot regulate unless there is some appropriate scientific protocol to judge whether there is risk involved. Regulation would just be a veneer without it.

According to the summary of their conclusions—and I am going through very quickly seven categories—on survival. They talk about whether recombinant organisms can survive in the environment. They say, nevertheless, it is not now possible to predict survival.

On growth, they talk a little bit about the whole idea of organisms and how they grow in the environment. They say "The current data base must be expanded to allow for accurate prediction of which types of organisms will and which will not proliferate."

On genetic transfer, on whether genetic material can be transferred from one organism to another organism in the environment, the study concludes "little information exists on gene transfer in nature."

Point four, on dispersal: How does an organism disperse in the environment? They conclude in this report "there is limited understanding of the traits contributing to successful dispersal."

Point five: Environmental effects. This is quite interesting, and let me read this—"Both the public sector and the scientific community are concerned with effects on natural communities and natural processes. While EPA has a research program on measuring effects of chemicals on such communities, products of biotechnology need to be evaluated in different ways from chemicals because these organisms are highly specific for the plants, animals and microorganisms that they may invade or harm, and the generalizations so useful in toxicology probably have little meaning for them."

On health effects they say EPA must develop a biotechnology health effects research strategy. It goes on and on and on.

The bottom line here is that we have not even begun to develop the rudimentary science of risk assessment in this country. It has not been done.

In the current issue of Scientific American, the June issue, I note the head of the ecology program of the National Science Foundation, Patrick W. Flanagan, is reported to have said—and this is a paraphrase from the magazine, not a direct quote from the scientist—that they report that he says "Until ways to gauge such environment risks are developed, large scale releases of genetically engineered microbes into the soil, air or water should not be done."

So issue No. 1 is: When are we going to start the process of developing a risk-assessment science? We are putting the cart before the horse in trying to rush this technology out into the environment before we have done the appropriate scientific homework to assure that these categories of risk assessment are set up.

This dovetails with issue No. 2; they are interrelated; they are yet unresolvable.

Issue No. 2—and the issue the American public, I believe, is concerned about, and increasingly Members of Congress—is the issue of insurance liability.

The fact is this industry is bare. They cannot get insurance for biotechnology product liability. They cannot get insurance from the insurance industry against sudden accidents that pollute the environment.

Now it is true, as we know, that there is an insurance crisis in this country, and that it is affecting many fields. But I should point out that genetic engineering is still, in many ways, distinct from the crisis that we are seeing in the insurance industry as it relates to chemicals and other products.

The reason is this: Genetically engineered products are much more analogous to nuclear products than either are to chemical products.

The reason is twofold. With both genetically engineered products—live products that can be introduced in the environment—like nuclear technology, there is only a small chance that you are going to have an accident with any given introduction. Whereas with chemical products there is a greater liklihood of more frequent accidents.

However, with genetic products that are alive and placed in the environment, and with nuclear technologies, even there is only a low probability of having an accident at any given time, if an accident does occur it can be irreversible and catastrophic.

There is another analogy to place here between the two product technologies. With both nuclear accidents and with genetic engineering accidents the damage continues indefinitely.

As we have seen from the Chernobyl disaster, the accident is going to cause damage with, I believe, the reports I have heard of, of a lifespan of 24,000 years; which is longer than recorded history.

With genetic engineering accidents if a microbe or an organism does find a niche and is destructive to the environment, it can maintain itself indefinitely, just like radiation. It can go on for generations and centuries.

Whereas a chemical accident, even something of the scope of Bophal, is containable. It can be cleaned up in a given duration of time, and the damage can be controllable and it can be ascertained.

That is not true with living organisms that invade the environment. It is not true with radiation.

Now in terms of an analogy, I found it interesting that we had no representatives of the environmental sciences here today. I would encourage this committee, and I hope you are considering this, to have future hearings to bring in the environmental sciences.

We have heard from the microbiologists, we have heard from the molecular biologists, and we have heard from industry and the White House; I think it is time to hear from the environmental sciences. I believe that they will probably have a different story to tell about the probability of accidents.

When we get to the question of insurance liability, we have an industry here that cannot get insurance; companies and universities are going to try to self-insure, or develop insurance pools. Believe me, no insurance pool, and no self-insured institution in this country can possibly absorb the liability of one catastrophic accident with genetic engineering comparable to something like chestnut blight.

That is an example of an exotic organism placed into this ecosystem, and within 10 years it destroyed the lumber industry for chestnut. And we are talking not about hundreds of millions, but about billions of dollars in terms of the long-term damage by that particular introduction of an organism.

We could cite you—and I would be glad to provide for this committee examples of other organisms, microbes, plants, animals—that cause harm in the hundreds of millions of dollars and billions of dollars because they were introduced into a nonnative system here in North America, and we cannot get rid of them.

If you are from the South, you are all too familiar with kudzu vine. If you are from the North you are very familiar with Dutch Elm disease and Gypsy moths.

I am concerned, and I think that the American public has a right to be concerned about the idea of self-insurance. The fact is, the reason the insurance industry cannot develop an appropriate methodology, or mechanism, to insure these products is there is no science of risk assessment that allows the industry to decide how to determine the premiums for different categories of organisms.

So these two issues are interrelated. No science of risk assessment; no insurance.

To my mind this whole exercise here in this room this afternoon is deja vu of what happened in 1955.

A young nuclear industry had not yet commercially developed. It came before Members of Congress, like yourselves. The nuclear industry said, look, we cannot get insurance against catastrophic accident. And because we cannot get insurance we cannot get investment. Therefore, we call upon Members of Congress to pass legislation to pass to limit liability.

That was 1955. I believe in 1957 the Congress of the United States passed the Price-Anderson Act. And do you know what? I have tried this out on people around the country. Not 1 person in 1,000 can tell you what that act is all about. I think they would be aghast if they knew what that act was all about.

In that act, as you know, an individual cannot bring a tort claim in Federal court on liability. I think the American public would be shocked to know that.

Second, under that act, the industry was required to pool together a certain sum of money that the Federal Government would then decide how to dole out.

Correct me if I am wrong, but I understand that Members of the House passed a bill on Price-Anderson increasing the liability from $550 million to $6 billion, or at least it is being considered.

Is that correct?—It's being considered, sorry, being considered.

Well, let's take a look——

Mr. VALENTINE. Being considered and passing are two different things.

Mr. RIFKIN. Right. [Laughter.] I understand that.

Let us take a look, then, at what this means in summary, here.

Are we going to allow an industry to proceed, and allow regulations in the Federal agencies to be put in place now which allow biotechnology companies to place organisms into the environment without a risk assessment science in place and without the question of insurance liability being even minimally addressed by either Congress or the Federal agencies?

My feeling on this is if we do allow this at this time, we allow these products to be rushed into the environment without the appropriate risk assessment science at least being developed, and without the question of insurance liability being adequately addressed, that we will be back here in hearings in a few years down the line when there are accidents, potentially catastrophic accidents.

In my mind, the question is not if an accident will occur, the question in my mind is only when. And when that moment comes I hope the American public is protected with the kind of regulations dealing with risk assessment science and insurance liability that I think they would want to see in place.

[The prepared statement of Mr. Rifkin follows:]

STATEMENT OF JEREMY RIFKIN
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BEFORE THE
SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND ENVIRONMENT
AND
THE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY
OF THE U.S. HOUSE COMMITTEE ON SCIENCE AND TECHNOLOGY
ON
"THE BIOTECHNOLOGY SCIENCE COORDINATION ACT OF 1986"

JUNE 4, 1986

On behalf of the Foundation on Economic Trends, we want to thank you for this opportunity to present our analysis of current efforts by government agencies to regulate biotechnology.

The federal government is faced with two overriding issues in regulating biotechnology. First, no science of risk assessment has been developed. Second, the question of insurance liability has not yet been adequately addressed. Until these two related concerns are properly assessed and resolved, it would be premature for any federal agency to authorize the release of live genetically engineered organisms into the open environment.

The White House proposal to coordinate federal agency regulation of biotechnology completely ignores these two central issues that are at the heart of the regulatory dilemma. Without a science of risk assessment, it is impossible to properly regulate the introduction of genetically engineered organisms into the biosphere. Yet, industry, the White House, federal agencies, and scientific bodies including the National Science Foundation and National Institutes of Health continue to advocate deliberate release experiments in advance of the development of even a rudimentary predictive ecology science.

I would like to point out to this committee that in January of 1986, the Biotechnology Study Group of the EPA Science Advisory Board issued a study concluding that, at this time, no adequate predictive ecology science presently exists. I would like to quote directly from the 7 major areas of concern covered in the EPA study.

1. Survival: Recombinant organisms may present a problem if they persist in the environment, and such organisms "to be used for pollution control must be able to endure. Nevertheless, it is not now possible to predict survival . . . ." Report, p. 2.

2. Growth: An increase in numbers of a few released microorganisms is likely to be necessary to cause an ecological or public health effect and "the current data base must be expanded to allow for accurate prediction of which types of organisms will and which will not proliferate." Report, p. 2.

3. Genetic Transfer: While a harmful recombinant organism may not itself survive or multiply, "the relevant genetic information could be transferred *in situ* to other organisms [and] [t]he latter might ultimately become harmful. . . . little information exists on gene tranfer in nature." Report, p. 2.

4. Dispersal: Sites for releases are "usually not . . . where [the organism] can bring about some deleterious change because of the absence of suitable host animals or plants, or the absence of suitable environmental conditions. Risk assessment thus requires information on the mechanics and likelihood of dissemination by insects or other animal vectors, through air or soil, by water transport, or by other means. . . . [yet] there is limited understanding of the traits contributing to successful dispersal." Report, p. 3.

5. Environmental Effects: "Both the public sector and the scientific community are concerned with effects on natural communities and natural processes. [While EPA has a] research program on measuring effects of chemicals on such communities . . . . [p]roducts of biotechnology need to be evaluated in different ways from chemicals because these organisms are highly specific for the plants, animals, and microorganisms they may invade or harm, and the generalizations so useful in toxicology probably have little meaning for [them].' Report, p. 3.

6. Health Effects: "EPA needs information and expertise in public health, communicable disease risks, and the relevant biomedical disciplines . . . . EPA must develop a biotechnology health effects research strategy . . . ." Report, p. 3.

7. Remedial Action: A means must be found to contain and possibly destroy a genetically engineered organism in the unlikely event that . . . the organism is found to be harmful. . . . attention [must] be given to containment and remedial action." Report, pp. 3-4.

For many years, the Foundation on Economic Trends has been urging federal agencies and scientific bodies to address the critical question of how genetically engineered organisms survive, grow, disperse, transfer genetic material and affect the environment and public health. These questions have yet to be addressed in any significant manner by the scientific community and the federal government. I note that, in the June 1986 issue of Scientific American, Patrick W. Flanagan, Head of the Ecology Program of the National Science Foundation, is reported to have said that "until ways to guage such environmental risks are developed, large-scale releases of genetically engineered microbes into the soil, air or water should not be done."

How then is it possible to regulate a technolgy without any substantive scientific basis for ascertaining environmental risk?

Because no risk assessment science currently exists for biotechnology, the insurance industry is unwilling to extend liability coverage for a wide range of genetically engineered products. At the present time, biotechnology firms and universities across the country are without liability insurance to cover sudden accidents that pollute or contaminate the environment. While it is becoming increasingly difficult to obtain liability coverage in many fields, genetic engineering poses a set of unique problems that are only analogous in nature to liability problems in the nuclear industry. With both genetic and nuclear technology, chances of an accident occuring are small. However, if an accident does occur, the event is potentially catastrophic and irreversible. As we have learned to our horror in the recent nuclear power accident in the Soviet Union, radioactive fallout can spread over large geographic areas contaminating the environment for thousands of years. Similarly, a dangerous genetically engineered microbe can mutate, reproduce, proliferate, and spread by wind dispersal and insect and animal transmission over vast areas of land. Like nuclear radiation, genetically engineered organisms persist in the environment indefinitely posing a continued threat to future generations.

In many respects, the current insurance crisis facing the biotech industry is deja vu of the insurance crisis faced by the nuclear industry in the mid-1950s. Unable to secure insurance against sudden catastrophic accidents, the nuclear industry successfully lobbied Congress to pass the Price-Anderson Act. That legislation precluded personal liability claims against nuclear utilities in the event of a nuclear accident or a meltdown. In addition, the utilities were required to establish a pool of hundreds of millions of dollars to be administered by the federal government in case of an accident. That figure has been increased to $6 billion by a bill passed in the U.S. House of Representatives a few weeks ago.

Like nuclear power, one catastrophic accident in the genetic engineering industry could result in damages in excess of hundreds of millions of dollars. No self-insured institution in the United States could effectively cover the liability claims of one genetic engineering accident comparable to the damage inflicted by organisms such as chestnut blight, dutch elm disease, kudzu vines, or gypsy moths.

In the coming decades, the biotechnology industry hopes to introduce hundreds and even thousands of new genetically engineered living organisms into the environment. While most of these introductions will pose no serious environmental hazards, sheer statistical probability suggests that a small percentage of these novel organisms will become serious pests threatening the long-term viability of our nation's ecosystems. The question is not whether there will be an accident but only when it will occur.

At the same time, I doubt very much whether the American public is going to be willing to give up its right to bring tort claims in federal court in the event of a biotech accident as it was forced to do with the passage of the Price Anderson Act governing nuclear technology. Moreover, I would like to know how the biotech industry hopes to secure an in-house pool of hundreds of millions of dollars to cover a potentially catastrophic accident. Therefore, the American public has a right to expect that the Congress of the United States and the Federal agencies give urgent attention to the insurance liability issue before a catastrophic accident occurs.

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Every great scientific and technological revolution in history comes packaged in the form of benefits and costs. The more powerful the technology is in promising an immediate economic benefit, the greater becomes the potential for long-term environmental, economic, and social dislocations. Genetic engineering provides civilization with the ultimate form of power over the forces of nature. We now have a technology at our disposal which allows us to begin intervening into the genetic blueprints of life. While there are many short term benefits to be derived from this emerging science, it would be naive and disingenious to believe that there will be no adverse impacts on the environment and human society. In a survey in the December 1985 issue of Science Digest, a hundred of the top scientists of the United States acknowledged the potential benefits of genetic engineering but warned that "its imprudent or careless use ... could lead to irreversible, devastating damage to ecology". These scientists say that genetic engineering technology poses a potential threat that could rival nuclear technology in the years to come.

Since World War II our government policy has narrowly focused on the question of potential benefit of new scientific and technological breakthroughs, with little or no attention paid to the long term environmental, economic, and social costs of new innovations. At the beginning of the nuclear technology revolution and the petrochemical revolution, the government failed to address the hard questions concerning potential externalities. As a result, our children's generation has been forced to deal with a mounting environmental, economic, and social bill ranging from nuclear waste dumps to acid rain.

Now with the emergence of the genetic engineering revolution, the federal government is once again failing to develop a coherent mechanism to assure a proper regard for the long-term health of the human and natural environments.

Today I would like to suggest a bold new departure in regard to this emerging scientific, technological and economic revolution. It is time for the federal government to contruct a regulatory procedure that takes into consideration the two fundamental issues that I have raised in this testimony. Until these issues are resolved, the U.S. government should refrain from authorizing the introduction of any genetically engineered organism into the environment.

Mr. VALENTINE. Mr. Rifkin, what are you really saying—and I do not want to go back and plow through what you have already said, and we appreciate your coming here to testify.

These others have questions and I am going to be very, very brief.

Are not you really saying that certain experimentation is, perhaps, necessary to see what the problems are, and that is even too dangerous. So are you saying that this whole area of biotechnology—that we should back off from it?

Mr. RIFKIN. No.

Let's take the second question first.

I am sure Members of this Committee are aware of the fact that there are certain parts of this technology that I have not critisized, or brought litigation at—against, or raised in public forum.

The whole question, for example, of pharmeceuticals, where you are not dealing—with exception of live viruses—the whole question of pharmeceuticals and the medical use of this technology does not raise the same fundamental environmental questions that are raised by releasing living organisms into the open environment.

I think what we have to do is distinguish between parts of this technology.

I am referring to regulation of that part of this technology that puts anything alive that is genetically engineered into the environment. And I take deep exception to the White House report, which I have had a chance to look at, which essentially deregulates this industry before Congress has even put regulations on.

We have here a White House report that was rubber-stamped—the biotechnology trade association's desires and the industry's desires—right down the line. They are eliminating from biotechnology regulation whole series of genetically engineered organisms that ought to be regulated and ought to have some kind of mechanism in place. So—I think that we have to distinguish between the two.

Now, in the other question you asked, Congressman—the question about how do we go ahead and develop a science of risk assessment if we don't do the experiments.

It is possible to do experiments on naturally occurring organisms—to check things like dispersal, genetic transfer, the fate of organisms. EPA, for example, has put out study proposals about a year ago, in Science magazine, requesting such working proposals by environmental scientists.

I understand that since that time EPA has quietly dropped funding for this predictive ecology methodology, and I think that is a shame.

Finally—you know, I find it quite interesting that in this country there is quite a bit of discussion in industry and among the scientific community—the molecular biologists—that if we don't do it, it will be done somewhere else. They point to Germany and Japan.

Well, I would like to point out to members of this committee that as far as I know, there is no—at the present time there are no plans afoot in Japan for deliberate releases of genetically engineered microbes or organisms; and second, in Germany, there is a moratorium. In Germany, the Parliament has a moratorium against any release of a genetically engineered organism in the environment.

So, I have been amused over the past few years to the idea that our Federal Government has been more stringent and more rigorous in its regulatory oversight in the question of deliberate release. That is just not the case.

Mr. VALENTINE. I have one question.

Traditional cross-breeding techniques have successfully developed literally hundreds of products which did not exist in nature. Now, don't such products carry the same risks of environmental disruption as genetically engineered organisms? And doesn't the risk stem more from novelty than from the process that creates the novelty?

Mr. RIFKIN. Well, I think you can find exceptions in either way you look at it, but I would say that, overall, the process of genetic engineering does raise significant and fundamental questions inherent to the process which have to be looked at, and that it would be remiss on the part of Congress and the Federal agencies to try and dismiss the overall importance of it as a genetic category and try and deal with each product as it comes along as if it were similar to naturally occurring phenomena, or to classical breeding phenomena.

There are distinctions to be made. We have had scientists provide affidavids in many of the litigations that we have been involved in—molecular biologists and environmental scientists—on the distinctions between genetic engineering and its impact as a methodology and naturally occuring phenomena. And I would be glad to provide affidavits and those statements by scientists to members of the committee.

Mr. VALENTINE. Representative Schneider.

Miss SCHNEIDER. Well, having spent since 9:30 this morning in research hearings, I will say that my frustration level has increased as the hours have moved along, and it seems to me that each of the panelists that we have listened to this afternoon are representing points of view that, by my looking at it, are quite extreme.

I find that exceedingly frustrating because, it seems to me, that here we have a technology with potential. And I, for one, happen to believe that we ought to be moving ahead with the utilization of this technology. Yet I have not heard any constructive specifics as to how we can go about doing that, and that is precisely what I am looking for.

I think that your examples and analysis comparing this industry with the nuclear industry—I would maybe say are 50/50 appropriate comparisons.

I think that our Government and the American people have been hoodwinked by the Price-Anderson Act, and a number of other things relating to this industry.

But on the other hand, I think that it is critical that as we look at, essentially, the demonstration phase—we are moving from the experimental into demonstration—that what we are looking for is not the grand-scale release of these organisms, but rather small scale.

My question to you, Mr. Rifkin, is how else do we assess the risks that are involved unless we begin on a small-scale level to actually permit these organisms to be released?

Mr. **Rifkin**. I share some of your frustrations, perhaps for other reasons.

First of all, I think there is a problem with the mandate of the agencies. You said that we should—we first have to deal with only small-scale releases.

The Environmental Protection Agency, by mandate, is not allowed to—and I am the person that asked them, in formal petition, to get involved in this process, much to my chagrin now a year and a half later—but under the experimental-use provision of FIFRA the Environmental Protection Agency is not allowed to consider a permit, an experimental-use permit, unless there is a feasibility that it is going to be used for commercial application. The EPA is not a research institution like the NIH.

So that in considering experimental-use permits that agency has to believe that the experiments being done are on the way to commercial application within a very short foreseeable period of time.

So I am very concerned that industry has taken the position in the last six months that we are only interested in small-scale release now. Because it is like the slippery slope of ethics, if you will.

Within a year, if these experimental-use permits are granted, they have to move toward commercial application.

So I think we have to take a look at both small scale and large scale. And I think one way to deal with the frustration is to do what I have been suggesting for years now.

And that is why do we not put a tremendous amount of research money in now, before we go ahead, and bring in the environmental scientists together with the molecular biologists. Let's get the entomologists out here, let's get the population geneticists, the microbial ecologists, the meteorologists, the veterinarians—let's get a whole range of biological scientists involved with the molecular biologists in trying to hammer out the first beginnings of a science of risk assessment.

And if these scientists then, after these kinds of collaberations, believe that they have enough information, quote unquote, at their disposal to develop certain generic categories of risk which might be, in their minds appropriate—then perhaps we can proceed.

But we have not done that.

And so I would like to know why the National Science Foundation has been dragging its heels. And the Office of Technology Assessment has talked about this; and the EPA and congressional hearings.

I am frustrated as hell about it.

Miss **Schneider**. Well, evidently in 1987 we have $2.5 million put aside for just this kind of research. So, there is that increase of $2.5 million which——

Mr. **Rifkin**. Is not very much.

Miss **Schneider** [continuing]. In light of what you just said is at least a step in the right direction.

Mr. **Rifkin**. It is a teeny little drop in the bucket.

In other words, the $2.5 million, if you take a look at the kind of studies that are required even for a rudimentary beginning, is an insult to the whole idea of developing a science of risk assessment.

If you are saying it is a step because there was no step before, yes; I agree with you.

Miss SCHNEIDER. Well, it seems to me that given the numbers we have on this committee, joint committee hearings—what are there, maybe 30 or so—there are 3 of us here today.

As far as I am concerned, we have not heard any constructive, specifics as to what we ought to do. And those who are gathered here in this audience are expecting a group of Members of Congress—at least three that are interested enough to be here—to come up with a solution. Which to my way of thinking is ludicrous.

Now, if the various witnesses that have come before this panel today feel that they are outside the government system, it is your own fault. Because if this is the Government by the people, of the people, and for the people then I expect to have a 5-point proposal of exactly what we ought to do and how we ought to do it. Because I certainly do not have the expertise to make these proposals, and it is quite clear that the other Members do not either——

Mr. RIFKIN. Yes.

Miss SCHNEIDER [continuing]. So I am feeling terribly impotent in terms of solving this problem. And I think it needs to be solved—we cannot continue to have the trade association which says everthing is fine, and you say everything is horrendous.

And so we are at a loggerjam here. We have to move ahead. I am asking all of the witnesses here today to give us some specific directions, because we are not moving.

Mr. RIFKIN. Yes.

Let me point out, just for the record, I have provided testimony with specific details in other hearings. Congressman Volkmer's hearings and Senator Gore's hearings last fall—specific detailed proposals on how Congress could legislate and how the Federal agencies could enact policy to oversee this technology.

The reason I emphasize the points I did today is that I think we have to get back to the broad overall generic problems. Because if we don't we are never going to resolve them.

I have a specific suggestion now—let's pass some legislation that would set up a meaningful program to develop risk assessment over a period of time and then see what can get. And after we get some results, then let's look and see whether we want to put anything in the environment.

I think that we don't want to repeat the lessons of the past with nuclear and petrochemical technology where industry and scientific establishment, hand-in-hand with Congress, said let's move into this. They did not give consideration to the hard questions that had to be asked up front. And as a result, we have a series of problems we have saddled our children's generation with—from acid rain to nuclear waste.

We do not want to repeat that problem here and I think Members of Congress share this concern. And the way to do that is to be prudent and ask the generic, fundamental questions first, and try and resolve them before we rush ahead and regulate without any kind of substance underneath it to make judgements on.

Mr. **Valentine**. Mr. Volkmer.

Mr. **Volkmer**. Yes; I won't take my full 5 minutes.

I have some disagreement with the gentlelady from Rhode Island as to what has been accomplished here today. And I think it has been very helpful as far as—especially the testimony from Dr. Schaechter and Dr. Riley concerning the organisms that should be subject to regulation. And I think that has been very helpful to us.

I agree also, I think, that Mr. Godown and Dr. Goldhammer have been very helpful as far as the structure of the type of regulatory body—regulations we should have; and the agreement that they should basically be the same, whether it is in USDA or EPA under FIFRA or TSCA, those type of things.

So I think it is—for one who has reviewed the bill that has been introduced by the chairman of the committee and then taking all of these things into consideration—I think I am coming pretty much to a position where I think I know where I am as far as what we need to be doing.

The only thing that is left out, that I feel disappointed in, is the fact that we have not had the opportunity to review the guidelines. To me, that is the opening up here that we need to do, and then I think we can put it all together and we can get on with it.

Jeremy, we have had discussions before and I understand your position. I, for one, agree that we need to make sure that before there is any release into the environment that it has to be safe to health—and I think we have some disagreement between us as to whether or not that can be done, or not done, without the research into the risk assessment factors.

I think we agree that we need to have that done.

We have had testimony on that. Our first panel there—Dr. Kingsbury—fully agreed that we need to have this done. But I do not believe that we should tell all of our industry that you are going to have to wait several years before we have this methodology to determine risk assessment worked out before we can go on—especially in those areas where we do already have availability of knowledge that we can have release.

Now, there has been one release already in which, I understand, you have not disagreed with.

Is that correct, Jeremy?

Mr. **Rifkin**. The Agracetus release?

Mr. **Volkmer**. Right.

Mr. **Rifkin**. Well, what I said is that that particular experiment, I did not feel, raised the same kind of fundamental questions that other organisms would have.

Someone then asked me, well, does that mean that you think that plants don't have any problems? Absolutely not. I think the Caigene experiment poses some big problems.

Mr. **Volkmer**. Right.

So you have to look at each one singularly, but there are those——

Mr. **Rifkin**. Develop genetic categories is what we need to risk assessment——

Mr. **Volkmer** [continuing].There are those that we could probably go ahead with without saying, no; we have got to do all the risk assessment first, though.

That is my point.

Mr. **Rifkin**. Well I think part of risk assessment—I agree—a part of risk assessment is setting up generic categories as to which experiments and categories of experiments would be most safe, and which would be most risky.

Mr. **Volkmer**. All right. Now——

Mr. **Rifkin**. And we have not even begun to really do a good job of that.

Mr. **Volkmer**. All right. I will not argue that. I agree that we are way behind in that area, and I think the witnesses today agreed that we need to provide the information and the methodology in order to do that.

The last thing I would like to comment upon in your testimony that gives me some concern—and I can understand your concerns. I have the same concern, but in the question of liability—if we required every company—let's take AGS and let's assume that we had a company out here that really had done what was right, and hadn't gone on the roof with the trees, et cetera, but had done everything that was right.

But there was a requirement in the law that that company would have to provide liability insurance for a worst-case scenario. My opinion—they would never be able to operate. It is gone, because they are not going to be able to afford—first they would not be able to afford it.

So we are saying that that is the end of that type of experiment.

Mr. **Rifkin**. Let me, if I may—we are talking here about an industry that is without insurance. Across the board.

And we are also talking about an industry that proposes to put hundreds and thousands of new genetically engineered organisms into the environment over the coming few decades.

As you know, Monsanto, an industry leader, says they are going to replace petrochemicals with renewable resources, genetically engineered. Obviously, when you introduce thousands of petrochemical products in the environment—most of them are benign, but a small, healthy percentage of them turn out to be real troublemakers for us and our children's generation.

It would be naive and disingenuous to think we are not going to see a repeat of that when we introduce hundreds and thousands of genetically engineered organisms into the environment.

But this time around, this industry that is emerging has no insurance. Not some insurance. Not adequate insurance. It is bare.

And I think we are going to be back here in these hearings—and I will on record on this—I don't care if it is 2 years or 3 years or 5 years, and there are going to be Members of Congress saying what happened, that we allowed an industry to go ahead where there is no insurance scheme in place and no regulations established by Congress or Federal agencies.

One accident is all it takes. And you do not need a worst-case scenario. You can have an organism out there and if it causes damage, just in a limited region, in the area of tens of millions of dollars. There are many companies that could not provide against the liability.

And I, for one, do not think it is inappropriate to demand some kind of resolution of the insurance question, when an industry wants to emerge in this country and begin to develop products wholesale in the environment without any insurance available.

Mr. VALENTINE. Mr. Ritter.

Mr. RITTER. Thank you, Mr. Chairman.

You know, in listening to you, Mr. Rifkin, I get the impression that if we had followed similar lines of reasoning in the early parts of the 20th century we would have never invented the automobile. Or we would never have brought the automobile out into mass production—I mean, here was this heavy, fast-moving element that could knock people over, explode because it was carrying a dangerous liquid. We probably wouldn't have had a car had we done this—the kind of preemptive technological evaluation that you are proposing.

Now, it would seem to me, too, that the care with which this technological evaluation is taking place is far, far in excess of the care of the technology assessment that occurred, or didn't occur, in a whole host of products that have come on the market, have changed our lives, and probably for the better.

You talk about petrochemicals—now, I know petrochemicals is a bogeyman. It is one of these—it is like a Salem witch, it has a polysyllabic, organic, chemical name to it—and it sounds terrible.

But believe me—your life, and the life of everybody in this room, in the balance, has been markedly benefited by petrochemicals. Including, you know, from gasoline to the shirt you are wearing.

But let me ask you——

Mr. RIFKIN. My shirt is cotton, actually. But a—[laughter]—a renewable resource.

Mr. RITTER. Great. Mine is polyester and cotton.

Mr. RIFKIN. Congratulations. [Laughter.]

Mr. RITTER. And I'm proud.

You know, you mentioned some examples of a gypsy moth, and a chestnut blight, and a Dutch elm disease. For the life of me, I do not see the relationship between that and a product that is—has been developed, it is a nonpathogen. How in the world do you compare a bug——

Mr. RIFKIN. Right.

Mr. RITTER [continuing]. Coming from another country on a tree, with a product engineered, out of a labratory, with a variety of safety constraints.

Why do you make that comparison?

Mr. RIFKIN. First of all, I would like to thank you, Congressman, for at least starting with the 20th century. I thought you were going to start by saying I suspect you would have been opposed to the wheel, or neolithic agriculture, which is what I usually get. I——

Mr. RITTER. I thought I would do you a favor. [Laughter.]

Mr. RIFKIN. Oh, thank you. At least you put me in this century, which is a decent thing to do.

There is a big difference——

Mr. RITTER. By the way, are you a microbiologist?

Mr. RIFKIN. No; I am not.

Mr. RITTER. Is that your training?

Mr. RIFKIN. No. We have——

Mr. RITTER. Are you a political doctor, or——

Mr. RIFKIN. No——

Mr. RITTER. What is your training?

Mr. RIFKIN. My background is in environmental science and philosophy of technology. We have a molecular biologist and environmental scientists who are consultants who work with us ongoing. And I rely on them——

Mr. RITTER. You have a doctorate degree in environment science?

Mr. RIFKIN. No. I rely on them the same——

Mr. RITTER. I am just curious.

What are your qualifications?

Mr. RIFKIN. My graduate work is in international affairs, economics, and philosophy. I have written 9 books on philosophy of science and technology, which have been translated in 12 languages and are used around the world. I lecture at universities each year. I have lectured on 10 percent of American universities, et cetera.

Mr. RITTER. But do you have a specific background in the molecular biology field——

Mr. RIFKIN. I do not. It——

Mr. RITTER [continuing]. Or microbiology field or some field that is pretty firmly associated with the subject at hand today?

Mr. RIFKIN. No, I do not.

And I would like to point out to the Congressman that Members of Congress do not have to be qualified as Ph.D's in the field to comment, or members of the public——

Mr. RITTER. Members of the Congress were never qualified [laughter]——

Mr. RIFKIN. May I finish, sir? You've asked me, may I finish?

You are qualified by being elected to the office. That is a qualification in and of itself. I do not doubt it.

But I don't believe one has to be a physicist to be able, as a responsible citizen, to critique, or to ask important questions about nuclear power or bombs.

I don't believe one has to be a chemist to ask critical and important questions of public policy relating to chemical pollution.

And I resent it, if this is the intent, that one has to be an expert in the field of molecular biology to raise serious questions about the environmental, social, and economic implication.

If that were the case, then none of the American people would be qualified to make any statements about any issue of which they are not an expert in the scientific field.

Mr. RITTER. Excuse me——

Mr. RIFKIN. Well, let me finish, sir, you asked me. And we would not have the kind of democratic republic that allows for public citizens to voice their concerns about pressing issues.

I notice that you did not ask——

Mr. RITTER. I don't think it is fair——

Mr. RIFKIN [continuing]. You did not ask the head of the industry association if they were doctorates in molecular biology——

Mr. RITTER. I wasn't here when they testified——

Mr. VALENTINE. Mr. Rifkin, let me say this.

Nobody questions your qualifications, or your right to be here, or your right to express yourself, so let's——

Mr. RITTER. Absolutely not. Absolutely not, I was simply asking——

Mr. RIFKIN. Well, I'm sorry, that is what I got from the line of questioning——

Mr. VALENTINE. Let's——

Mr. RITTER. No, I was simply asking whether you had a scientific background in this particular field, and——

Mr. RIFKIN. And as I responded to you, sir, we have scientists who——

Mr. RITTER. And I don't think——

Mr. RIFKIN [continuing]. Work ongoing with our foundation who provide all of that expert testimony——

Mr. VALENTINE. Let's move along, gentlemen, I think you have answered the question——

Mr. RITTER. I——

Mr. RIFKIN. I would like to answer the remaining questions of this Congressman, if possible, since he asked them.

You asked what is the distinction to be made between the automobile and genetic engineering.

Mr. RITTER. No, I asked about a beetle, a gypsy moth, and a blight.

Mr. RIFKIN. Yes, let me get to that. Let me get to each one of your questions, Congressman, and try to answer them. I suspect you asked them because you wanted an answer from me.

The difference between an automobile, for example, and genetic engineering, I should point out to you, Congressman, is that with an automobile there is insurance requirements. There is insurance liability requirements, and that is a requirement of law.

Second, in relation to the question about the difference between gypsy moths and genetically engineered organisms, I would like to aquaint the Congressman with testimony that has been provided in front of House and Senate committees, which I am sure you've perused, over the last 3 years in which scientists have shown what the similarities are.

And they are these. Scientists have used the analogy of exotic organisms because these are organisms that are nonnative to our ecosystems. They are placed into our ecosystems from other parts of the world, and some of these organisms find a niche and they become destructive and they maintain themselves for long periods of time.

The analogy with genetically engineered organisms, as has been testified in congressional hearings by distinguished environmental scientists, is simply this: With a genetically engineered organism, even if you are taking a naturally occurring organism and changing a genetic instruction, that potentially places the organism in the category of a novel organism. It is being placed into an environment that it did not develop in terms of its evolutionary——

Mr. RITTER. Does the gentleman have examples where—I mean, you have to go a little bit on the basis of history. Does the gentleman have examples of these kinds of organisms that have been introduced in the environment that have had similar effects to the gypsy moth, or to the Dutch elm disease—I mean, what are the examples the gentleman is providing?

Mr. **Rifkin**. Congressman, I am sure you are aware that we have not released any genetically engineered organisms into the environment, with the exception of the pseudo-rabies virus. And so environmental scientists who have testified before these congressional hearings for several years have said that the best of their expertise, and their opinion, that there is a comparable analogy with the introduction of exotics—nonnative organisms.

Now, the Congressman might want to take exception to these experts. I would suggest that it might be helpful for this committee to invite some of the environmental scientists here in the United States to testify before the committee so that they could inform you of their opinions on this issue.

I think it would be helpful for all concerned here.

Mr. **Ritter**. Well, you know, Mr. Chairman, if I might just proceed for a moment.

The gentleman has stated that he does not believe that risk assessment is in yet the appropriate stage which it can be used to evaluate the safety of these products.

Is that correct?

Mr. **Rifkin**. No, it is not.

What I have done is reiterate—that is correct, but I have reiterated the conclusions of the Environmental Protection Agency task force on the question of predictive ecology, and I quoted verbatim from their text where they said that we do not have even minimum, or adequate, information in the seven categories that we would have to have to determine how an organism interacts, whether it would be safe or not in the environment. And I would be glad to provide that to you.

Mr. **Ritter**. Does the gentleman say that there can be no small-scale releases in the environment until insurance is available?

Is that the kind of comment that you made?

Mr. **Rifkin**. I believe that it would be irresponsible for any Federal agency to authorize any experiment into the environment until we have adequately addressed two questions. The beginning question of risk assessment, and second, the question of liability.

And I would remind the Congressman——

Mr. **Ritter**. This is a catch 22. If you don't have risk assessment developed to a sufficient level to define total safety, and then you don't have insurance——

Mr. **Rifkin**. No one is talking about total safety.

Mr. **Ritter** [continuing]. And you can't introduce something until you have insurance—I mean, how are we going to ever make any credible introductions——

Mr. **Rifkin**. Good point. It is a good point——

Mr. **Ritter**. And does risk assessment mean 100 percent risk-free?

Mr. **Rifkin**. No, you cannot have 100 percent risk-free, but you can develop the beginning of some probabilities. And it is possible to model a predictive ecology—this is an important question you raise—it is possible to model a predictive ecology using naturally occuring phenomena. And many of the studies and many of the suggestions for studies have suggested that we model a predictive ecology based on using naturally occuring phenomena to get a data base.

We have no data base because the environment sciences have not been encouraged or financed to do this kind of research.

So, I think the question is an admirable question, and the answer is we need to encourage the scientific community to use naturally occuring phenomena to develop a data base from which to judge the release of genetically engineered phenomena.

That is what is required now, at this time.

Mr. RITTER. What you are saying is, until some time as this data base——

Mr. RIFKIN. The beginning of one, yes.

Mr. RITTER [continuing]. Is available, no small-scale releases are acceptable?

Mr. RIFKIN. Well, as I said in response to Congressman Volkmer's query on the question of Agricetus, I believe that there are generic categories that are going to be safer than others.

But I believe that if we really want to be responsible on this, we would at least begin to develop a science of risk assessment.

The amount of time we spent, just in hearings alone, battling on this for the last 3 years, we could have gotten together and started such a study.

There has only been one meeting held between environmental scientists and microbiologists in this country on the whole question of developing an environmental risk assessment science, back in 1985 in Philadelphia. One meeting.

Miss SCHNEIDER. Would my colleague yield?

Mr. RITTER. Yes, I most certainly will yield.

Miss SCHNEIDER. How do the recommendations that Mr. Rifkin is making dovetail with your piece of legislation calling for risk assessment?

Mr. RITTER. Well, I think it dovetails quite well, because we have legislation that would seek to promote the advancement of the science of risk assessment, understanding that it is an imperfect science.

But, you know, that legislation hasn't passed. Risk assessment is being used. In many cases it has provided the sole science base to regulatory decisions. We could stack up a pile of regulatory decisions larger than the Capitol Building because the techniques of risk assessment are not yet totally and completely developed. We should go ahead and develop them.

But to say that we await the advancement of this science and the advancement of this technology in the commercial marketplace—we await that pending the achievement of a perfect science of risk assessment is going to be awaiting a cold day in hell.

Mr. RIFKIN. Congressman Ritter, please, I am not calling—I want this for the record, and I know it is late in the day—but please understand, I did not say, nor have I ever said, we need a perfect risk assessment science. Nor have I ever said we need a totally predictable risk assessment science.

For God's sake, all I am saying is let's begin to develop the rudimentary protocols to set up generic categories of risk before we release the first microbes into the environment.

I don't find that to be an extreme statement. I don't find that to be an inappropriate statement. I find it to be a prudent, commonsensical approach to this situation.

And I don't—for the life of me, I can't understand why there is such a rush to move ahead with experiments before we have even begun to develop the rudiments of such a science.

Mr. **Ritter**. Well, I might add that history shows that there are certain fields of endeavor that are reasonably safe, because they have been reasonably safe. And that they can be predicted to be reasonably safe, and that some small, on a case-by-case basis introduction, given the fact that we have had very substantial overview by the scientific community of the research base, that it simply seems to be common sense to move ahead slowly and deliberately without bureaucratizing this thing to death.

Mr. **Rifkin**. Well, not only has it not been bureaucratized to death, but there hasn't been any regulations placed on this industry.

What we are doing, your Federal agencies are primarily using existing regulations in order to squeeze in an entire emergent technology revolution. And they are asking for even existing——

Mr. **Ritter**. Some of these existing regulations make some sense given that there are certain similarities in the commodity to be regulated——

Mr. **Rifkin**. Well, I am not normally a betting man, but I'll bet—I would like to little gentleman's bet with the Congressman. I would be willing to make a bet that within five years from now——

Mr. **Valentine**. I wonder, Mr. Rifkin—we want to stay at least within spitting distance of the five minute rule.

I wonder if you could make a private bet with him——

[Laughter.]

Mr. **Rifkin**. More than happy to.

Mr. **Valentine**. Let me—I think your position is clear. We have to conclude at some time. I want to be fair with my colleague, and with you, too.

Let me say that tomorrow morning, at 9:30, in room 2318, we will hear from environment scientists, and this hearing is adjourned.

[Whereupon, at 5:55 p.m., the hearing was adjourned, subject to the call of the Chair.]

THE BIOTECHNOLOGY SCIENCE COORDINATION ACT OF 1986

THURSDAY, JUNE 5, 1986

HOUSE OF REPRESENTATIVES, COMMITTEE ON SCIENCE AND TECHNOLOGY, SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE RESEARCH AND ENVIRONMENT, AND SUBCOMMITTEE ON SCIENCE RESEARCH AND TECHNOLOGY,
Washington, DC.

The subcommittees met, pursuant to call, at 9:45 a.m. in room 2318, Rayburn Office Building, Hon. James H. Scheuer (chairman of the Subcommittee on Natural Resources, Agriculture Research and Environment) presiding.

Mr. SCHEUER. Good morning. Yesterday, we had the first of two hearings on H.R. 4452, the Biotechnology Science Coordination Act. We will have the second of our two hearings on that subject today, and continue testimony. Yesterday we heard from a variety of witnesses—from scientists, from an activist, from a representative from the White House Office of Science and Technology Policy, and their testimony addressed some of the cross-cutting and complex issues surrounding this bill.

Today, we will be examining in closer detail the effects of these issues and the proposals in the bill, and the effect of the proposals in the bill on the EPA, the Department of Agriculture, and particularly, we will be looking at the question of whether existing laws give EPA and the U.S. Department of Agriculture sufficient authority carefully to assess the risks of planned release of genetically engineered organisms before they take place, before the release takes place.

We look forward to this morning's testimony, and I am pleased to welcome as the first witness this morning, our colleague from Missouri, Harold Volkmer, who is chairman of the sister committee which is cosponsoring this hearing, the chairman of the Investigations and Oversight Subcommittee of the Science and Technology Committee. We very much appreciate the opportunity to have the benefit of Chairman Volkmer's testimony, and his considerable experience and thoughtful views on the biotechnology issues.

We are happy to have with us Shelly Boehlert, our distinguished colleague who is the ranking Republican on the Science Research and Technology Subcommittee.

OK, Congressman, we are delighted to have you. We welcome you. Take such time as you may need, and perhaps we will have some questions.

STATEMENT OF HON. HAROLD VOLKMER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

Mr. VOLKMER. Thank you very much, Mr. Chairman.

Mr. SCHEUER. Of course, your prepared testimony will be printed in full at this point in the record.

Mr. VOLKMER. Thank you.

I appreciate the opportunity to testify today about the Federal Government's role in the regulation of biotechnology. I believe that biotechnology holds great promise for this Nation and the world. The potential of genetic engineering to enhance our lives has led companies in this country and abroad to spend millions of dollars to develop and market a wide variety of products that only a decade ago were beyond our dreams.

However, the ability to alter the genetic makeup of living things presents undeniable risks. While chemicals and even radioactive products can be isolated and contained, genetically engineered organisms are alive and procreate. These organisms once released into the environment, have the capacity to spread and dominate with as yet unknown consequences. They cannot be recalled.

A staff report prepared for the Subcommittee on Investigations and Oversight in February 1984, during the chairmanship of the Honorable Albert Gore, Jr., concluded that release of genetically engineered organisms into the environment posed a "low probability of high consequence risks" and that the then current Federal Regulatory framework did not guarantee that adequate consideration will be given to potential environmental effects of a deliberate release."

Obviously, we cannot afford to rely on hindsight to determine whether biotechnology products released into the environment have dangerous side effects associated with their beneficial use. If we in Congress are to build and maintain the public confidence necessary for the acceptance and success of biotechnology in this country, we must see to it that there is in place a clear and effective system to determine whether particular genetically engineered organisms are safe before they are released in nature.

The first level of Federal review of biotechnology was established by the guidelines of the National Institutes of Health Recombinant DNA Advisory Committee, the RAC. These guidelines pertained to laboratory practices in experiments involving recombinant DNA technology. Voluntary compliance with the guidelines was widespread and is no doubt responsible for the pristine record of safety associated with genetic engineering laboratory research.

The next substantial government action regarding biotechnology came about in December 1984 when various Federal agencies published in the Federal Register a coordinated framework for the Federal regulation of biotechnology. Each agency involved with the regulation of biotechnology products described how products developed through recombinant DNA technology would be reviewed under existing statutes and regulations.

The Federal Government's interim guidelines were put in place in the nick of time; for by December 1984 several companies were already proposing to conduct field trials of genetically engineered organisms. As early as 1983, one company, Agracetus, applied to the NIH RAC for approval to field test a genetically engineered tobacco plant. A court decision in a law suit brought by Jeremy Rifkin, concerning a different field test, resulted in the requirement that NIH perform an environmental assessment of any impact of any proposed field test prior to approval. Because of this delay, Agracetus then applied to USDA for permission to field test the plant. USDA, however, stated only that the plant was not a plant pest according to the Federal Plant Pest Act and therefore the field test posed no problem.

This non-decision by USDA prompted Agracetus to return to the NIH RAC which approved the field test of the plant in 1985. Agracetus began the field test this week in Wisconsin.

Another company, Calgene, applied directly to USDA for approval to field test a different type of genetically engineered tobacco plant. That application, although similar to the one submitted by Agracetus, was reviewed by the Agricultural Recombinant DNA Research Committee of USDA, ARRC, rather than the Animal Plant Health Inspection Service, APHIS, which had reviewed the application submitted by Agracetus. No action has yet been taken on Calgene's application.

The lightening rod that drew public attention to biotechnology was EPA's approval in November 1985 of a field test by Advanced Genetic Sciences, Inc. (AGS) of a genetically engineered bacteria to prevent frost formation on strawberry plants. This action by EPA, and the confused state of affairs at USDA, as seen by the regulatory limbo of the Agracetus and Calgene applications, prompted the first of what proved to be a series of hearings by the Subcommittee on Investigations and Oversight.

The first hearing was held on December 4, 1985, 1 year after publication of the interim guidelines and less than 1 month after approval of the ice minus experiment by AGS. The purpose of the hearing was to examine the Federal Government's preparedness to regulate and review the products of biotechnology. Specifically, the subcommittee wanted to examine the process EPA followed in approving the AGS field test, and wanted to learn how USDA intended to resolve the regulatory confusion that had surfaced within USDA.

USDA's regulatory posture under the interim guidelines received additional attention at this hearing following the release of a GAO report commissioned by Hon. Don Fuqua, chairman of the House Science and Technology Committee. That report revealed that USDA was funding 87 projects nationwide that could lead to the deliberate release of genetically engineered organisms, the majority of the releases to occur within the next 5 years. Only three of the projects involved formal programs of risk assessment.

At the hearing, industry representatives testified that delay and confusion among and within the agencies was handicapping U.S. companies in the international race to develop and market biotechnology products. EPA and USDA officials admitted that there had been initial uncertainty in implementing the interim guidelines. However, EPA cited its scientific review of the AGS proposal as an example of how EPA would examine future field test proposals.

EPA felt that, in the AGS review, it had adequately ensured that the environment was protected while not unduly delaying the field testing necessary to develop and market a new biotechnology product.

USDA representatives discussed how USDA proposed to coordinate review of biotechnology products among the various divisions at the agency. Proposals for research and field testing would go first to the ARRC, which would then refer the proposal to the appropriate division of APHIS. Because the ARRC is composed of representatives from both USDA's Science and Education Division and the Marketing and Inspection Division, USDA believed that the previously confusing and overlapping jurisdiction of those two divisions would be resolved.

Altogether, the testimony at the hearing presented a picture of regulatory certainty and thoroughness. Even more encouraging was the assertion by the agencies and by OSTP, that the new regulatory guidelines would be published in the Federal Register by January 31, 1986. Off the record, they still aren't final.

Unfortunately this picture evaporated within a few short months. In February 1986, the subcommittee learned that AGS had conducted unauthorized tests with the ice-minus bacteria on trees located on the open rooftop of its office building in Oakland, CA. In addition, these tests which were intended to determine if the bacteria was pathogenic to fruit trees, were not performed under controlled conditions as stated in the company's application to EPA, thereby making the data from the tests suspect.

The subcommittee convened a hearing on March 4, 1986 to investigate these allegations. The company asserted that a tree was a contained facility and therefore EPA authority was not needed for the test. EPA vigorously denied this. As for the use of data obtained from invalid experiments, a member of EPA's Science Advisory Panel that reviewed and approved the AGS proposal testified at the hearing that he could not have approved the field test had he known that the pathogenicity data had been obtained under uncontrolled conditions.

The hearing brought out another troubling fact. The supposedly remote testsite for the field test was in fact the backyard of an AGS official who lived in a residential neighborhood. EPA, it seems, had never visited the site to confirm its remoteness. In fact, neither EPA nor AGS had discussed the proposed testsite with the Board of Supervisors of Monterey County, CA, where the site was located or with neighboring citizens. As a result, the county invoked its zoning power to block the testing within the county. EPA has since suspended the permit, initiated administrative action against AGS and fined the company the maximum permitted under FIFRA.

EPA's lax oversight of the details of the AGS test, the unauthorized release of the bacteria on the company's roof, and the company's reporting of scientifically invalid data completely undermined EPA's testimony from the December hearing that the interim guidelines were being effectively implemented. The confusion surrounding the definition of crucial terms such as "contained facility," "release" and "remote" demonstrated that the Federal Government had not done a thorough job in establishing the guidelines for the regulation of biotechnology.

A month after the AGS hearing, the subcommittee learned that USDA had licensed a genetically engineered live virus veterinary vaccine without review of the vaccine by the ARRC, supposedly the focal point of USDA's Biotechnology Review Program. The subcommittee's investigation revealed several disturbing facts.

First, the inventor of the vaccine, Dr. Saul Kit of the Baylor College of Medicine, had participated in a field test of the vaccine on 1400 pigs in Texas without notifying, or receiving the approval of, the Institutional Biosafety Committees [IBC] at the Baylor College of Medicine and at Texas A&M, as required by the NIH RAC guidelines.

Second, USDA did not classify the vaccine as a recombinant organism until after the license applicant, Techamerica Group, Inc., had field tested the vaccine in several midwestern States.

Third, after USDA classified the vaccine as a recombinant organism, it did not submit the license application to the ARRC for review. This omission directly contradicted the testimony USDA provided at the December hearing regarding review procedures within USDA. Finally, USDA did not publish an environmental assessment of the effects of releasing the genetically engineered vaccine before it licensed the vaccine.

The facts surrounding licensing of the vaccine demonstrated once again the confusion regarding definition. Dr. Kit maintained at the hearing that the vaccine was not a recombinant organism since it contained no foreign DNA, and that inoculation of a pig with the vaccine was not a release. However Dr. Kit may defend this opinion, which is not necessarily shared by the Baylor IBC, the Texas A&M IBC or NIH officials, the fact remains that Dr. Kit, like AGS, chose not to consult with the appropriate Federal and local officials for approval of what was unarguably a test outside of a laboratory of a product developed through recombinant DNA technology. Baylor and Texas A&M have investigated Dr. Kit's possible violation of the NIH guidelines. NIH is currently conducting its own investigation.

This pioneer behavior regarding the release of biotechnology products undermines the public confidence in biotechnology that had been created by industry's voluntary compliance with the NIH RAC guidelines governing laboratory research. This lack of public confidence can be seen in the actions of local governments that have acted to halt biotechnology experiments in their areas. Citizens in Tulelake, CA, are opposing an EPA-approved field test of the ice-minus bacteria on potatoes. In my district in Missouri, St. Charles County government recently informed Monsanto that a proposed field test of a genetically engineered pesticide would violate the county zoning code. Who can say that these actions by local governments are not the direct result of the public's lack of confidence in biotechnology stemming from the incidents I have described today.

The Monsanto application to field test a genetically engineered pesticide also brought out a new reality in Federal regulation of biotechnology. EPA has delayed permit approval until Monsanto repeats certain safety tests that EPA scientists felt were inadequately done initially. Even though EPA's Science Advisory Panel recommended permit approval based on other valid safety tests, EPA decided to require Monsanto to go the extra mile to prove to EPA and the public that the field test would be safe.

No doubt AGS' lack of candor with EPA helped trigger this increased scrutiny of Monsanto's application. Although Monsanto has announced it would not do its field test this year, I agree fully with EPA's insistence on complete, valid scientific testing of genetically engineered organisms proposed for release to the environment.

The hearing by the Investigations and Oversight Subcommittee has identified three problems that must be addressed in any successful system of Federal review and regulation of biotechnology. First, there is the problem of definition. What is a release into the environment, a contained facility, and what is a genetically engineered organism? Until there is agreement on these definitions, there will be unending confusion about what should be regulated and when.

Second, there is the problem of jurisdiction, both interagency and intraagency. There is presently no clear understanding of which agency is responsible to review which products, and, in the case of USDA in particular, there is considerable confusion regarding which internal group has or should have review responsibilities. Finally, there is the problem of attitude; that is, how will the Government approach the regulation of biotechnology? It is clear that the public will not accept the attitude that a new technology is safe until proven otherwise. Love Canal and Chernobyl have eliminated that option altogether.

The Government's attitude must be fair not only to industry but to the taxpayer. The burden of proving safety should be done by those who have produced a product and who will profit from its use. This burden should be consistent across the various Federal agencies and there should be as little duplication of effort, overlapping jurisdiction, and delay as possible.

The new Federal guidelines promised for January 31, 1986, are now long overdue. They have been promised time and again, and in fact were approved by the administration's Domestic Policy Council on May 20, but the White House refuses to release them or to allow Agency officials to discuss them before Congress. This delay not only hurts the biotechnology industry by postponing administrative clarification of the Federal regulatory policy; it also hurts public confidence in biotechnology by giving the appearance that the guidelines cannot stand the light of day and cannot be subjected to open discussion at these hearings.

I am determined to see to it that the guidelines get a full airing in the public before Congress. Therefore, I intend to convene a hearing of the Investigations and Oversight Subcommittee on these guidelines whenever the White House releases them. It is regrettable enough that the guidelines were developed in private meetings closed even to staff scientists at EPA and USDA.

What is needed now is a full, public examination of the assumptions and details of these very important guidelines. I welcome the participation of the Natural Resources, Agriculture Research and Environment Subcommittee and the Science, Research and Technology Subcommittee at that hearing.

While the administration delays, the Congress has taken the initiative in forming a formal national regulatory system for biotechnology. Congressman Fuqua's bill, the Biotechnology Science Coordination Act of 1986, creates a clear and certain pathway for biotechnology products to travel from the lab to the market. The act's three-tiered permit system accents scientific review and data gathering at different levels of use and distribution.

It also creates a joint Government industry research program to investigate some basic questions related to the effect of releasing genetically engineered organisms into the environment. I recommend two general changes in the bill as it now reads.

First, the definition of genetically engineered organisms should be expanded so that all products of recombinant DNA are scientifically reviewed before they are released into the environment. We simply do not have the environmental data to assume that some genetically engineered organisms are automatically safe to release. Second, the permit systems the bill creates should be established by a separate, independent act rather than by amendments to TSCA and the USDA statutes. This will streamline the implementation and alteration of the permit system as time goes by.

The history of Federal involvement in the regulation of biotechnology is an inconsistent one. No one disputes the great value of the NIH RAC guidelines for biotechnology research. Those guidelines relied on cooperation more than coercion, caution rather than prohibition. Unfortunately, it is easier to enforce guidelines in a laboratory than in a field. When genetically engineered organisms are released into the open, the environment itself becomes the laboratory. Therefore voluntary guidelines and blind faith won't do. Yet, Federal review of deliberate releases has been either too little, as in the AGS case; too late, as in the vaccine case; or not at all, as with the Calgene application lying dormant within USDA for so long and now temporarily suspended.

The Federal Government must fill its role in biotechnology and fill it soon. That role requires the Government to conduct the best scientific review possible of genetically engineered organisms proposed for release into the environment to ensure that each organism holds the key to a treasure, not Pandora's box. We have already asked future generations to clean up our toxic chemicals and nuclear waste. Let's not add genetically engineered organisms gone astray to the list.

Thank you very much, Mr. Chairman.

Mr. **Scheuer**. Thank you, Mr. Chairman. We are into a rollcall vote, and we will take another 5 or 6 minutes until we all have to leave for the vote, and then we will resume the questioning after we come back, if that is agreeable to you.

Mr. **Volkmer**. Yes; that is fine.

Mr. **Scheuer**. Mr. Chairman, yesterday the Industrial Biotechnology Association testified that they weren't at all concerned that university researchers were exempt from regulation under TSCA, the Toxic Substances Control Act, because they said universities are subject to the voluntary constraints in the guidelines of the National Institutes of Health, the NIH. Is it your view that the Congress has given NIH the job of protecting the environment and the NIH is likely to focus in on this mission?

Mr. **Volkmer**. I disagree with that statement to some degree—to the degree that it is research being done by NIH funding and only laboratory research, then I would agree with it, but beyond that, I disagree that research being done outside NIH grants by a university, say, in conjunction with a private industry that is not funded through NIH. I seriously question it, especially any research that may lead to an application for a release under TSCA, because TSCA, itself, has loopholes in it.

Mr. SCHEUER. Was NIH effective in reviewing and authorizing the release of the pseudorabies vaccine?

Mr. VOLKMER. No, they were not. That was only USDA. Even though—just to give you some idea, if I remember right, Dr. Kit, in his operation on research at Baylor, had received some NIH funding prior to that and Baylor does receive NIH funding, but yet we see where that fell right through the crack, and they went ahead with the field test.

Mr. SCHEUER. In other words, wouldn't you conclude—I don't want to put words in your mouth, but isn't it reasonable to conclude that neither EPA nor the USDA have the statutory authority to require university researchers to submit proposed releases of genetically engineered organisms to either EPA or USDA for review before they are released.

Mr. VOLKMER. Only if there is research being funded by the agency. Outside research, I feel, would not be necessarily controlled by USDA. In other words, USDA does fund and is funding some genetically engineered projects right now. I don't know whether EPA is or not, but those that were funded, just like NIH funded, they could have control over those. But as far as research outside the funding of those agencies, no, there would be no control, and we need some statutory authority.

Mr. SCHEUER. Congressman Boehlert from New York.

Mr. BOEHLERT. I just want to thank the chairman for a very comprehensive statement. Just one quick question. I know we have a rollcall underway. Do you think the void in the Office of Science Adviser to the President, a void that is now filled, has been responsible for the delay?

Mr. VOLKMER. I really don't know if that is the cause of it or the fact that, you know, the guidelines have been developed over a period of time. I know there is some, perhaps disagreements within the certain agencies, too, as to how these guidelines sort of affect that specific agency, and that's why I am anxious to see the guidelines because what I am afraid I am going to see, part of what I am going to see, is that you follow a different procedure with EPA than with USDA. You follow a different procedure under FIFRA under EPA than with TSCA under EPA.

Mr. BOEHLERT. You have the same feeling that I do that the guidelines are imminent? I know we have heard that before.

Mr. VOLKMER. I hope they are imminent.

I think it would be very helpful, to answer your specific question, that if we had had a director in the OSTP that I think things would have probably been handled a little better.

Mr. BOEHLERT. Thank you very much.

Mr. SCHEUER. We will suspend for about 12 or 13 minutes for the rollcall vote.

[Recess.]

Mr. SCHEUER. The subcommittee will come to order. We will proceed with our witness list. The first witnesses will be Dr. Orville Bentley, Assistant Secretary of Agriculture for Science and Education, and Mr. Alan Tracy, Acting Assistant Secretary of Agriculture for Marketing Inspection.

All right, who is the spokesman?

Dr. BENTLEY. I am.

Mr. SCHEUER. OK, why don't you take 6 to 7 minutes and speak to us informally, hitting the highlights of your testimony, Dr. Bentley, and be assured that your testimony will be printed in full at this point in the record.

STATEMENT OF DR. ORVILLE BENTLEY, ASSISTANT SECRETARY FOR SCIENCE AND EDUCATION, ACCOMPANIED BY ALAN TRACY, ACTING ASSISTANT SECRETARY, MARKETING INSPECTION, DEPARTMENT OF AGRICULTURE

Dr. BENTLEY. Thank you, Mr. Chairman. We appreciate the opportunity to talk about new technologies as they relate to agriculture, and we want to recognize and express appreciation for your interest in the safe and efficient use of biotechnology. Genetic engineering and other aspects of biotechnology hold a great deal of promise for the American farmer and for consumers, as it has been said earlier today at this hearing.

As we pursue these new research areas, we must do so with the precaution to insure that any associated risks are aborted. Two years ago, we began to formulate a coordinated Federal policy on biotechnology, and we will implement the provisions of this policy as soon as the President approves it.

You have asked us to discuss the U.S. Department of Agriculture's view on H.R. 4452. Before I do so, I would like to make one or two general comments. First, we will set out the premise that there are really two aspects of biotechnology. The research aspect and product regulation. I have responsibility for administering the program of agricultural research and education conducted or funded by USDA, and with me today is Alan Tracy, the Acting Assistant Secretary for Marketing and Inspection Services. The agencies under Mr. Tracy are charged with the responsibility to regulate and license certain agricultural products.

Mr. Chairman, in view of the progress which has been made by the executive branch in the formulation of a system to coordinate and regulate biotechnology within the context of existing statutes, the Department does not support enactment of H.R. 4452. By way of a detailed explanation, you asked if USDA has clear and sufficient authority to review all genetically engineered agricultural products involving both research and commercial applications. The Department has extensive authorities upon which it can rely to implement its biotechnology policy.

In my statement, I list those authorities, and I will not read them at this time. I believe these statutes give the Department ample authority to meet the needs of our biotechnology program, and we plan to closely monitor the implementation of our biotechnology policy in the context of these statutes.

Your second question involved the proposed establishment by H.R. 4452 of an Agricultural Recombinant DNA Advisory Committee within USDA. There is such an interagency committee referred to, ARRC, and it is in place in USDA at this time. Under the new policy, this committee would be known as the Agricultural Biotechnology Recombinant DNA Advisory Committee or ABRAC. The ABRAC will perform many of the functions outlined for the ARRC proposed by H.R. 4452.

The Department will also establish the Committee on Biotechnology in Agriculture, or we will refer to it as the CBA. The CBA, which will be chaired jointly by the Assistant Secretary for Marketing and Inspection Services, and the Assistant Secretary for Science and Education, will function both as a policy body in the USDA and a bridge between its research and regulating structures. The CBA will be composed of representatives of USDA agencies involved in biotechnology.

The ABRAC, which is analogous to the ARRC, composed of public and private sector members, will be an official peer review body to advise the Secretary on scientific and technological issues relating to biotechnology research, and as called upon, the scientific aspects of regulatory functions. It will be a committee chartered under the Federal Advisory Committee Act. ABRAC review will be conducted in a manner that avoids conflict of interest while assuring protection of confidential business information. It is ABRAC which will have responsibility for making recommendations on issues of approval for research projects.

Your third question related to the handling of application involving genetically engineered organisms, including any confidential business information submitted to the agency. The answer to this question is twofold: Applications for approval of research projects will be directed to the Office of Agricultural Biotechnology which was created by Secretary Lyng to provide USDA with the mechanism to coordinate all facets of biotechnology in agriculture. This office will report to me, and will provide staff support for the research and regulatory functions.

Our review procedures will be comparable in many cases to the NIH RAC that has been referred to already today, and we will gain a great deal of experience and guidance in how we formulate our program by drawing on the experience of the RAC. APHIS or the Animal Plant and Health Inspection Service has issued policy statements on the protection of privileged and confidential business information, and that will be used as a guide in the continuation of the work in the Department.

Your final question centers on what changes could be made in H.R. 4452 to facilitate USDA's review and regulation and the agricultural products of biotechnology. Mr. Chairman, rather than deal with specific provisions of the bill, let me state that we view the structure outlined in H.R. 4452 as both cumbersome and inconsistent with the Federal biotechnology policy.

Once again, I commend the Committee on Science and Technology for the continuing interest in the development of biotechnology. Our mutual goal to establish an American biotechnology industry that produces products that will benefit society and not endanger its environment is best achieved by the scrutiny that is given by the press, academia, the public, the executive branch of our Government, and by the Congress. However, the U.S. Department of Agriculture, for the reasons outlined here, does not support enactment of legislation at this time.

This is our statement. We would be pleased to answer questions, sir.

[The prepared statement of Dr. Bentley follows:]

STATEMENT OF ORVILLE G. BENTLEY, ASSISTANT SECRETARY FOR SCIENCE AND EDUCATION, U.S. DEPARTMENT OF AGRICULTURE

Mr. Chairman and members of the committee, the U.S. Department of Agriculture [USDA] appreciates the interest and concern you have expressed in making certain that new technologies are indeed safe and efficient. Genetic engineering and the other aspects of biotechnology hold great promise for the American farmer and the consumer. As we pursue these new research areas, we must do so with precaution to insure that any associated risks are avoided. Two years ago we began to formulate a coordinated Federal policy on biotechnology. We will implement the provisions of this policy as soon as the President approves it.

You have asked that I discuss the U.S. Department of Agriculture's view of H.R. 4452, the Biotechnology Science Act of 1986. Let me first set out the premise that there are two aspects of biotechology: Research and product regulation. I have the responsibility for administering the programs of agricultural research and education conducted or funded by USDA. With me today is Alan Tracy, Acting Assistant Secretary for Marketing and Inspection Services. The agencies under Mr. Tracy are charged with responsibility to regulate and license certain agricultural products.

At the conclusion of my statement, we will be pleased to respond to any questions you might have. My remarks are made for the Department as a whole.

Mr. Chairman, in view of the progress which has been made by the Executive Branch in the formulation of a system to coordinate and regulate biotechnology within the context of existing statutes, the Department does not support enactment of H.R. 4452. By way of a detailed explanation, you asked if USDA has clear and sufficient authority to review all genetically engineered agricultural products involving both research and commercial applications. The Department has extensive authorities upon which it can rely to implement its biotechnology policy. These authorities include: the Food Security Act of 1985; the Virus-Serum-Toxin Act; the Federal Plant Pest Act; the Plant Quarantine Act; the Federal Noxious Weed Act; the Federal Seed Act; the animal quarantine laws; the Plant Variety Protection Act; the Federal Meat Inspection Act; and the Poultry Products Inspection Act. I believe these statutes give the Department ample authority to meet the needs of our biotechnology program, and we plan to closely monitor the implementation of our biotechnology policy in the context of these statutes.

Your second question involved the proposed establishment by H.R. 4452 of an Agricultural Recombinant DNA Advisory Committee [ARAC] within USDA. There is, as you are aware, an interagency committee, the Agricultural Recombinant DNA Research Committee [ARRC] in place within USDA at this time. Under our new policy, this committee would be known as the Agricultural Biotechnology Recombinant DNA Advisory Committee [ABRAC]. ABRAC will perform many of the functions outlined for the ARAC proposed by H.R. 4452.

The Department will also establish the Committee on Biotechnology in Agriculture [CBA]. The CBA, which will be chaired jointly by the Assistant Secretary for Marketing and Inspection Services, and the Assistant Secretary for Science and Education, will function both as a policy body in the USDA and a bridge between its research and regulating structures. The CBA will be composed of representatives of USDA agencies involved in biotechnology issues. The ABRAC, (which is analogous to the ARAC), composed of public and private sector members, will be an official peer review body to advise the Secretary on scientific and technological issues relating to biotechnology research, and as called upon, the scientific aspects of regulatory functions. It will be a committee chartered under the Federal Advisory Committee Act. ABRAC review will be conducted in a manner that avoids conflict of interest while assuring protection of confidential business information [CBI]. It is ABRAC which will have responsibility for making recommendations on issues to issuance of approvals for research projects.

Your third question relates to the handling of applications involving gernetically-engineered organisms, including any confidential business information [CBI] submitted to the agency in support of any application. The answer to this question is twofold: Applications for approval of research projects will be directed to the Office of Agricultural Biotechnology [OAB] which was created by Secretary Richard E. Lyng to provide USDA with the mechanism to coordinate all facets of biotechnology in agriculture. This office will report to me, and will provide staff support for the research and regulatory functions.

As has long been the practice of the Department, and consistent with the National Institutes of Health Recombinant DNA Research Advisory Committee [NIH-RAC], the sucurity of CBI will be assured. Applications for product licenses and permits will continue to be processed by APHIS, which routinely handles CBI in a manner which provides proper protection to the applicant.

We would like to note that on September 23, 1985, USDA's Animal and Plant Health Inspection Service [APHIS] issued a policy statement on the protection of privileged or confidential business information (50FR 38561-35563). This policy establishes requirements for control of documents received by APHIS that contain such information concerning biotechnology. These established procedures conform to Freedom of Information Act [FOIA] requirements for both protection and disclosure.

Your final question centers on what changes could be made in H.R. 4452 to facilitate USDA's review and regulation and the agricultural products of biotechnology. Mr. Chairman, rather than deal with specific provisions of the bill, let me state that we view the structure outlined in H.R. 4452 as both cumbersome and inconsistent with the Federal biotechnology policy.

Once again, I commend the Committee on Science and Technology for the continuing interest in the development of biotechnology. Our mutual goal to establish an American biotechnology industry that produces products that will benefit society and not endanger its environment is best achieved by the scrutiny that is given by the press, academia, the public, the executive branch of our government, and by the Congress. However, the U.S. Department of Agriculture, for reasons outlined here, does not support enactment of legislation at this time.

Thank you for giving USDA this opportunity to share with you our views on this critical topic.

Mr. SCHEUER. Thank you, D. Bentley. Dr. Bentley, in your view, do you now have statutory authority to review, before release, genetically engineered crop plants such as corn or tobacco, that is not a pest?

Dr. BENTLEY. Well, sir, we do have, and I think I have to make a bit of a caveat as to the conditions. First, in traditionally agriculture——

Mr. SCHEUER. Either you have that jurisdiction——

Dr. BENTLEY. Yes, we do have with regard to research that is being developed and carried on, say, in the agricultural experiment stations, the universities, the Federal agencies and so on, that would be reviewed before released, and we have that authority.

Mr. SCHEUER. Well, that is U.S. funded research. How about private researchers like Monsanto Chemical Co. and other large agribusiness developers?

Dr. BENTLEY. Under the science and education caveat, no, we would not have the authority to ask for the review. However, when——

Mr. SCHEUER. You do have the authority to review them prior to release.

Dr. BENTLEY. Right, but if they——

Mr. SCHEUER. Don't you think you ought to have that authority?

Dr. BENTLEY. Yes, we would have it, as I——

Mr. SCHEUER. But you don't have it now; is that correct?

Dr. BENTLEY. Yes, we would have it when it comes time for licensing. Now, one thing—this would be a very important caveat——

Mr. SCHEUER. Look, I just want a clear answer on that matter, OK, because I only have like 5 minutes and I have Miss Schneider.

Dr. **Bentley**. If it is a pest it has to be reviewed.

Mr. **Scheuer**. You do not have the authority, the statutory authority, to review before release privately developed genetically engineered crop plants that are not pests like corn and tobacco. Is that a clear statement.

Dr. **Bentley**. The answer is. yes, as I understand it, if it is not pest.

Mr. **Scheuer**. The answer is, no, you do not have that authority.

Dr. **Bentley**. I was answering yes to your question.

Mr. **Scheuer**. Do you have any different answer, Mr. Tracy?

Mr. **Tracy**. No, and of course if it has no prospect of being a pest, I don't see why it is a problem.

Mr. **Scheuer**. You can see no problems that come from genetically engineered crops that are not pests? You see no possibility of a problem?

Mr. **Tracy**. No.

Mr. **Scheuer**. All right. Do you have jurisdication now to review before release genetically engineered organisms where it is not known whether they are pests or not produced like a private developer like Monsanto Chemical? Yes or no?

Mr. **Tracy**. If there is any prospect that it may be a pest, we have the authority, yes.

Mr. **Scheuer**. How do you know without review in a new genetically engineered product, whether that prospect exists or not. If you haven't reviewed it, how do you know? And if you don't have authority to review it, don't you think you ought to have authority to review it in order to determine whether there is a prospect that it might be a pest?

Mr. **Tracy**. Well, we do have the ability to review it to determine whether or not there is a prospect that it might be a plant pest. Of course, if someone releases something and says that it isn't a plant pest, and it becomes a plant pest, then they have got some real problems and so do we.

Mr. **Scheuer**. Do you have the authority in the absence of knowledge that it is a pest to review a genetically engineered product developed by a private company before released?

Mr. **Tracy**. If its status is unknown——

Mr. **Scheuer**. Yes.

Mr. **Tracy**. We have the authority to require that that review be made to determine whether there is any prospect that it will be a pest, and we have been undertaking that sort of a review.

Mr. **Scheuer**. I would like for you to provide a written—are you a lawyer, Mr. Tracy?

Mr. **Tracy**. No.

Mr. **Scheuer**. Well, I would like for you to provide a written response to that question with the assistance of your department's legal staff so that we have a clear statement of whether you think you now have the legal jurisdiction, the legal authority to require review of a genetically engineered substance which may, or may not, be a pest which you have no imperical evidence that it is a pest, but which may be a pest. Do you have legal authority now to require that review before release.

Mr. **Tracy**. Yes, sir.

Mr. SCHEUER. And we would like it to be a semi-legal memorandum, not a discursive layman's memorandum.

Mr. TRACY. We would be happy to provide that.

[The information follows:]

United States
Department of
Agriculture

Office of
General
Counsel

Washington,
D.C.
20250

JUN 25 1986

MEMORANDUM

TO: Alan Tracy
Acting Assistant Secretary
Marketing and Inspection Services

FROM: John Golden
Associate General Counsel

SUBJECT: Authority to Regulate Genetically Engineered Plants Pursuant to the Federal Plant Pest Act when their Plant Pest Status is unknown.

At a hearing on June 5, 1986, Mr. James H. Scheuer, Chairman of the Subcommittee on Natural Resources, Agriculture Research and Environment, of the House Committee on Science and Technology, asked you whether the Department had statutory authority to regulate genetically engineered plants when the plant pest status of such plants was unknown. You responded that the Federal Plant Pest Act (FPPA) (7 U.S.C. §§ 150aa et seq.) provided authority to regulate such genetically engineered plants, and added that proposed regulations covering such genetically engineered plants had been drafted by the Department and were awaiting publication. The Chairman requested a legal analysis of the Department's authority, pursuant to the FPPA, to regulate such genetically engineered plants. This memorandum responds to your subsequent request for our opinion as to the Department's authority to regulate genetically engineered plants, pursuant to the FPPA , when the plant pest status of such plants is unknown.

The judicial system has "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." Chevron U.S.A. v. Natural Resources Defense Council, 467 U.S. 837, 843 (1984); Aluminum Co. of America v. Central Lincoln Peoples Util. Dist., 467 U.S. 380, (1984); Blum v. Bacon, 457 U.S. 132, 141 (1982). "When a court reviews an agency's construction of the statute which it administers, it is confronted with two questions. First, always, is the question whether Congress has directly spoken to the precise question at issue . . . If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute . . . as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." Chevron v. NRDC, 467 U.S. at 842-843. The Department's construction need not be the only permissible construction or even the conclusion a review court would have reached. FEC v. Democratic Senatorial Campaign Comm., 454 U.S. 27, 39 (1981).

After review of the FPPA and its legislative history, we have concluded that the language of the Act and its legislative history allow the regulation of genetically engineered plants pursuant to the Act, when the plant pest status is unknown. That review and discussions with your staff about the rationale for regulating such genetically engineered plants convince us that the Department's interpretation is consistent with the legislative intent of the FPPA and is a reasonable construction of the Department's statutory responsibilities under that Act. The Department's construction is sufficiently rational to preclude a court from substituting its judgment for that of the Department's. Young v. Community Nutrition Institute, No. 85-664, slip. op. at 7 (Sup. Ct. June 17, 1986).

The FPPA was enacted to fill gaps in the Department's authority to protect American agriculture against invasion by foreign plant pests and diseases. It confers very broad authority on the Secretary of Agriculture to prevent the dissemination into the United States or interstate of plant pests. Section 103 the FPPA provides that:

> (a) No person shall knowingly move any plant pest from a foreign country into or through the United States, or interstate, or knowingly accept delivery of any plant pest moving from any foreign country into or through the United States, or interstate, unless such movement is authorized under general or specific permit from the Secretary and is made in accordance with such conditions as the Secretary may prescribe in the permit and in such regulations as he may promulgate under this section to prevent the dissemination into the United States, or interstate, of plant pests. (7 U.S.C. § 150bb(a)).

"Plant pest," is defined as any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, or parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants. (7 U.S.C. § 150aa(c)) (emphasis added).

Although this "can injure" language could be read to limit the authority of the Department under the FPPA to regulate only organisms which the Department has already determined are harmful to plants, in our opinion this narrow reading would fail to take into account the broad definition of "plant pest" and the clear congressional intent in enacting the FPPA to fill a gap in previously existing law. H. Rep. No. 289, 85th Cong. 1st Sess. 2 (1957).

The House report stated:

> The purpose of ... the bill is to fill a gap which has existed for a number of years in the authority of the Department of Agriculture to protect American agriculture against invasion by foreign plant pests and diseases ... under existing law the Department has the authority to regulate the importation or the interstate movement of any insects in a live state which are notoriously injurious to cultivated crops. Id. at 2 (emphasis added).

Further, the House Report, under a section entitled "Additional Authority Needed," explained that, in addition to providing authority to regulate organisms that "can injure" plant or plant products, the FPPA provides authority to regulate organisms that might later be found to be injurious to cultivated crops. In this regard, the House Report stated that Department authorities existing before enactment of the FPPA:

> ... do not provide authority to regulate the movement into or through the United States of insects that might later be found to be injurious to cultivated crops, or of mites, nematodes, protozoa, bacteria, fungi, parasitic plants or reproductive parts thereof, and viruses, which can injure or cause disease or damage in plants or their products. Id. at 3 (emphasis added).

The House Report states that the FPPA was enacted (1) to correct deficiencies in the Insect Pest Act (repealed), the Plant Quarantine Act (7 U.S.C. §§ 151 et seq.), The Mexican Border Act (7 U.S.C. § 149), and the Mollusk Act (repealed); and (2) to protect American agriculture against invasion by foreign plant pests and diseases, which, in the language of the FPPA, are "new to or not theretofore known to be widely prevalent or distributed within and throughout the United States." Id. at 3 and 9. The FPPA authorizes the issuance of regulations to prevent the dissemination into the United States or interstate of plant pests, in any situtation in which such regulations are not authorized under the Plant Quarantine Act. (7 U.S.C. § 150ee).

The proposed regulations for genetically engineered organisms are structured to prevent the release into the environment of genetically engineered organisms which are plant pests or which there is reason to believe are plant pests. The Department believes that the release of such genetically engineered organisms into the environment, is tantamount to the introduction of a plant pest which is "new to and not theretofore known to be widely prevalent or distributed within and throughout the United States." It is necessary to regulate such releases to prevent the dissemination into the United States or interstate of plant pests.

The FPPA was envisioned by American nurserymen as the statute which would create a "first line of defense" at the border and the ports of entry. Plant Pests, Control and Eradication, 1957: Hearing on H.R. 3476 Before the Subcomm. on Research and Extension of the House Comm. on Agriculture, 85th Cong., 1st Sess. 29 (1957) (statement of Richard P. White, Vice-President Am. Assoc. of Nurserymen). The Department has incorporated this "first line of defense" philosophy into its proposed regulations for genetically engineered organisms. The Department interprets the FPPA as mandating those measures necessary to prevent the introduction or dissemination of plant pests. It is within the Department's power to formulate policy and make rules to fill any gap left, implicitly or explicitly by Congress. Chevron v. NRDC, 467 U.S. at 843; Morton v. King, 415 U.S. 199, 231 (1974).

The Department has determined it is necessary to regulate unclassified or unknown organisms in order to prevent the introduction or dissemination of plant pests. Many types of organisms, particularly microorganisms, were unknown until recent years, including groups of fungi, bacteria, viruses, and viroids. In every group, a significant number of plant pests is now found.

Genetically engineered plants for which the plant pest status is unknown may be regulated for similar reasons. It has long been recognized that plants (nursery stock) present unique plant pest risks. On July 31, 1947, Congress amended the Plant Quarantine Act of August 20, 1912 (7 U.S.C. §§ 151 et seq.), to give the Secretary of Agriculture broad authority to prohibit entry without a permit of all nursery stock regardless of plant pest status. (7 U.S.C. § 154). This amendment also provided authority for post entry quarantine of that nursery stock permitted entry. (7 U.S.C. § 154). Congress reasoned that this added degree of protection was an important safeguard against pests which are not detectable by inspection. S. Rep. No. 102 80th Cong., 1st Sess. 3 (1947). Past experiences with Kudzu vine, the starling, the gypsy moth, and chestnut blight, coupled with the unknown potential effects of releasing into the environment genetically engineered plants for which the plant pest status is unknown support the reasonableness of the decision to regulate such genetically engineered plants.

It is clear that the potential benefits of genetically engineered plants are numerous, including increased yield, improved plant quality, nitrogen fixation, and disease resistance. See, e.g., Office of Technology Assessment, U.S. Cong., Impacts of Applied Genetics: Microorganisms, Plants, and Animals (1981). However, the novelty of genetically engineered plants and the lack of experience with them makes it more difficult to predict their impact on agriculture and the environment. See, e.g., Staff of House Subcomm. on Investigations and Oversight, Comm. on Science and Technology, 48th Cong. 2d, Sess., The Environmental Implications of Genetic Engineering (1984).

In view of these circumstances it appears that a decision not to regulate such genetically engineered plants would be contrary to the congressional intent of preventing the introduction and dissemination of organisms that "might later be found to be injurious." Plant Pests, Control and Eradication, 1957: Hearing on H.R. 3476 Before the Subcomm. on Research and Extension of the House Comm. on Agriculture, 85th Cong., 1st Sess. 15 (1957). Where the congressional intent is clear that intention is law and must be given effect. Chevron v. NRDC, 467 U.S. at 843: FEC v. Democratic Senatorial Campaign Committee 454 U.S. at 32.

"If Congress has explicitly left a gap for the agency to fill, there is express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such ... regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." Chevron v. NRDC, 467 U.S. at 844; United States v. Morton 467 U.S. 822, 834 (1984). It should also be noted that the Supreme Court has held that statutes providing broad authority may be held to encompass products of new technology never envisioned by Congress when the statutes were enacted. Diamond v. Chakrabarty 497 U.S. 303, 315 (1980).

It is therefore our opinion that the Department's interpretation of the FPPA as providing the authority to regulate such genetically engineered plants and organisms is a permissible construction of the Act.

Mr. **Tracy**. An example of where that was done is in the case of the Agracetus proposal where we made a formalized review and determined that there was no real significant risk of that becoming a pest, and therefore there was no need for them to apply for a permit from us.

Mr. **Scheuer**. I am informed that in that case you simply determined that it wasn't a pest and you let it go.

Mr. **Tracy**. We determined that it wasn't a pest and decided that there was no need for them to apply for a permit.

Mr. **Scheuer**. Did you do any tests, or you felt that there wasn't any need even for real serious scientific review?

Mr. **Tracy**. I am informed that the data was already there, and we did not have to do a test.

Mr. **Scheuer**. How about in the case—do you have the legal authority to review before release the development by a private firm of genetically engineered animal biologics such as bovine growth hormone?

Mr. **Tracy**. Well, I am not sure that I would classify that as animal biologic, but to answer your question without the reference to bovine growth hormone, we do have that authority. We do not as yet have our regulations in place to deal with intrastate movement under the Virus-Serum-Toxin Act. We do have the authority granted in the farm bill, or the Food Security Act, that was passed in December 1985, and we will be coming forward with regulations to implement that authority for intrastate movement. We currently only have it for interstate.

Mr. **Scheuer**. When will you have it for intrastate movement?

Mr. **Tracy**. Soon. We are working on the——

Mr. **Scheuer**. What does soon mean?

Mr. **Tracy**. A matter of weeks rather than months.

Mr. **Scheuer**. Within 30 days?

Mr. **Tracy**. Well, we expect to have proposed regulations out for comment and review. I'm not sure about within 30 days, but I would say it is a matter of weeks, rather months.

Mr. **Scheuer**. Well, that would mean less than 30 days, wouldn't it?

Going off the record, let me explain a little bit of skepticism that I have. I authored an amendment to the Atomic Energy Act. It is now known as the Nuclear Regulatory Commission, but then it was known as the Atomic Energy Act—prohibiting the transport by air of plutonium. The AEC came in and testified that they—oh, until the AEC represented to Congress, certified to Congress that they had a safe container that could stand the shock, the explosion, the heat, of an air accident of a highflying aircraft with a container carrying plutonium.

The AEC came in and said that we didn't need to do this; that they were days, certainly not more than weeks away from being able to certify that. Well, I said there won't be much of a loss of time, then. Let's go ahead to legislation. Well, they protested wildly, and it passed the House. They went around talking to Senators, and said it is absolutely unnecesary. We are within a matter of days or a week or two of being able to certify that.

Well, it passed the Senate and it was signed by the President, so they did prohibit the shipment of plutonium by air until the AEC certified to Congress that they had a safe container. It took them just about 10 years. So without bringing your personal credibility into question at all, with due respect I am asking you for a timeframe, a specific timeframe.

Mr. TRACY. All I can tell you is that it is a very high priority with the regulatory writing staff, and we do expect it to be fairly soon. I'm sorry I can't pin it down any further than that.

Mr. SCHEUER. Fairly soon.

Mr. TRACY. Fairly soon, weeks rather than months. I'm sorry I can't do better.

Mr. SCHEUER. Will you let us know when you have that, send us a copy?

Mr. TRACY. Yes, sir, with delight.

Mr. SCHEUER. Can you give us any reason—give us your justification of why USDA can't regulate plants in the same way that you regulate animal biologics.

Mr. TRACY. We think we have stronger regulations in place in the case of plants. In fact, we expect to have published proposed new regulations under the Plant Pest Act that are written and will be ready to go, hopefully within the next week or so that will strengthen further our authorities under the Plant Pest Act that will grant us authority to require a permit for any field test of any plant which has any possibility of becoming a plant pest.

Mr. SCHEUER. Do you have any idea when these guidelines are going to be out?

Mr. TRACY. I understand that question was addressed at length yesterday with those who are a little bit closer to the process now than we are.

Mr. SCHEUER. I wouldn't say at length. It was a passing reference to it now.

Mr. TRACY. USDA did have its portion of the policy statement completed in April. We have modified it a couple of times briefly since, but it is well ready, and as soon as that review is finalized in the White House, we are as eager to have it on the street as you are, sir.

Mr. SCHEUER. So the problem is in the White House now.

Mr. TRACY. Well, we hope it is no problem. I think we are happy that the President has taken an interest, but the fact is it has been delayed a little bit longer than we thought, and we wish it were——

Mr. SCHEUER. Well, we are always happy when the President takes an interest in our work.

Congresswoman Schneider.

Miss SCHNEIDER. I am interested in knowing that as we are moving ahead toward commercialization of a variety of genetic products, are there any other gaps that you haven't mentioned so far in your discussion with Mr. Scheuer, any other gaps in authority that you see that need to be addressed that are not currently?

Mr. TRACY. No.

Miss SCHNEIDER. You think you have pretty much got all bases covered.

Mr. TRACY. I think so. As I mentioned on the plant side we are very far along, and we are already requiring permits for a field test, and under VST it will take some time for those regulations to be finalized because you do have to go through a formal rulemaking process, but we feel with the passage of the Food Security Act of 1985 that we do have adequate authority in both of those areas of regulation for release. The language is under the Plant Pest Act for any field test, and under the Virus-Serum-Toxin Act, it is any movement of any animal biologic, but we have adequate authority to regulate.

Miss SCHNEIDER. Dr. Bentley, yes.

Dr. BENTLEY. Could I add to this? One thing that we can draw on a great deal of experience about handling of crops. Let's take a plant—and it is easier for me to describe it if we take a specific plant such as corn. Through biotechnology, once might alter its resistance or enhance its resistance to a disease or an insect. The introduction of however this would be done would introduce into the plant on a targeted basis a specific genetic makeup. That corn plant would essentially be the same as before, only it would have in it his enhanced ability to do that, which we have done in the past through long and intensive and very time consuming and very costly research in plant breeding. So we would then be looking at whether or not it performed the same as other corn plants and what its survival would be and so forth.

In the case of research, we have a system we worked out of testing that on a restrained basis or a controlled basis so we would know where we were, much as we have done before.

Miss SCHNEIDER. I have two other questions, but I would like to very quickly get an education from you on a plant that was introduced into this country, I think, from Japan, and I believe that it was called kudzu. Is that the proper name of the plant?

Mr. TRACY. Kudzu?

Miss SCHNEIDER. Kudzu. Why was it brought here?

Dr. BENTLEY. I'm not——

Miss SCHNEIDER. Intentionally or nonintentionally.

Dr. BENTLEY. Whether it was intentional or not, let me tell you my understanding why it was brought here. It was brought here at the time when we were trying to cope with excessive soil erosion in some parts of the United States, and it was considered a plant, and it is a plant that has a great deal of ability to establish itself——

Miss SCHNEIDER. Root system.

Dr. BENTLEY. Yes. Now, it is not a genetically developed plant.

Miss SCHNEIDER. But yet it is a plant, and I think many people would refer to it as a pest, and I think that sort of touches on the question Mr. Scheuer was asking that in certain circumstances, certain kinds of plants brought to certain environments can get out of control. Now what is the status of that particular plant now? Has the Department of Agriculture been doing anything to genetically devise a way or otherwise to control its growth?

Dr. BENTLEY. I don't know what is being done on it. I know it is of very grave concern in certain locations, and there is an effort to remove it. Whether or not there is other research being done on biotechnology to cope with it, I don't know. Maybe Mr. Tracy does.

Mr. TRACY. I wouldn't know on the research, but I do understand that it was brought in intentionally. Our new proposed regulations under the Plant Pest Act would allow us to regulate any unknown or unclassified plant.

Miss SCHNEIDER. OK.

Mr. TRACY. Or organism actually, not just plants, because other organisms can be plant pests besides plants.

Miss SCHNEIDER. OK, user fees. The Environmental Protection Agency has indicated that for licensing purposes of pesticides and some other chemicals, they are considering user fees. Is this something that your agency is thinking about?

Dr. BENTLEY. Not at this time. Now there might be an exception to that, but I don't know of one at this time.

Miss SCHNEIDER. Well, yesterday we had some lengthy discussions on risk assessment, and I noted that the General Accounting Office has reportedly indicated that you folks were funding very few projects involving risk assessment. I am sure you are probably aware of that GAO report.

Dr. BENTLEY. Yes.

Miss SCHNEIDER. And I wonder if you are doing anything to change your research program in view of that report.

Dr. BENTLEY. I would like to make two comments, and one is that on earlier times there have been various studies conducted at the National Academy of Science that the U.S. Department of Agriculture contributed funds to talking about risk assessment and setting up some guidelines much as the same ones that EPA and others have used in the past.

In terms of risk assessment, we think we are doing this on a continuing basis. In our research we have been looking at questions about what happens when you introduce or have a change in the plant or introduce plants in terms of the soil, what happens to the microbes in the soil, what happens to the ability of that plant to take over, say, an area. We have looked at these in the past, and will continue to do so in the plant area.

In the case of where microbes are introduced into the soil, there will be careful and detailed studies being done as we have done in the past to see what happens to them in terms of viability. We will do such things as putting in biological markers so that we can actually find out what happens to these kinds of organisms that are placed in the soil.

Mr. TRACY. Let me answer on my side on user fees.

Miss SCHNEIDER. Yes.

Mr. TRACY. I have 13 different legislative proposals that have been forwarded to the hill for user fees within my own area alone, and will provide for the record whether any of those would touch on licensing or permit.

[The material referred to follows:]

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

July 9, 1986

Honorable Claudine Schneider
House of Representatives
Washington, DC 20515

Dear Congresswoman Schneider:

On June 5, 1986, the Subcommittees on Natural Resources, Agriculture Research and Environment, and Science, Research and Technology of the Committee on Science and Technology held a joint hearing on biotechnology. During that hearing you asked if the Department of Agriculture proposes to assess user fees in any area that may affect biotechnology.

The Department transmitted a legislative proposal to Congress on April 30, 1986, that authorizes the collection of fees for certain animal and plant health inspection services. Included in that proposal is authority to assess fees for the licensing of animal biological products and the facilities that manufacture those products. While this proposal is not directed at genetically engineered organisms, fees would be charged for any animal biological product that is produced through biotechnology. We believe the costs associated with these activities should be borne by the persons directly benefiting from the activities of the Department and not by the general public. The proposed legislation has not yet been introduced in Congress.

We appreciate the opportunity to respond for the record and will be happy to respond to any further questions from you or other members of the Committee.

Sincerely,

Alan T. Tracy
Acting Assistant Secretary
Marketing and Inspection Services

Miss **Schneider**. OK, thank you. Thank you, Mr. Chairman.

Mr. **Scheuer**. Chairman Volkmer.

Mr. **Volkmer**. Thank you very much, Mr. Chairman.

Dr. Bentley, Mr. Tracy, when the GAO was making their study, Dr. Shibley outlined a schedule or a guideline for review of any genetically engineered biological product within USDA—submitted to USDA. One was to look at the NIH guidelines. I suppose you would look at your own now. Design a risk analysis, and then APHIS biotechnology working group would look at it. The ARRC, which is now the ABRAC, would look at it, and then consult with NIH and then publish a request for release in the USDA review process under Federal regulations.

That information is taken from the interviewers' notes with Dr. Shibley. Now is that what is in the present proposed guidelines for USDA, that type of procedure?

Mr. **Tracy**. I don't think the proposed guidelines for USDA, for the policy statement, go into that kind of detail. The environmental assessment, though, that was done with regard to the pseudorabies vaccine does lay out that process, I think, very well. That would be a good source as to how we proceed with handling licensing applications.

Mr. **Volkmer**. OK, to continue on with that same type of thing, I notice we will just have to wait, I guess, to take a look at it, but will genetically engineering plants proposed for release be reviewed by the ABRAC under the guidelines?

Dr. **Bentley**. The answer is yes.

Mr. **Volkmer**. Mr. Tracy.

Mr. **Tracy**. I presume some will. I think what you mean to ask is will all genetically engineered plants proposed for release be reviewed by the ARAC and it is a possibility that some would not. If we had concerns of confidential business information, we would be proceeding with our review under the Plant Pest Act, and we might or might not in some circumstances take it to the ARAC or ABRAC once it is—there is a difference now, again, of whether you are talking about a license application for commercialization or whether you are talking about research. And if it is federally funded research, the answer is, yes.

Mr. **Volkmer**. I am talking about a licensing application. I understand what federally research is. USDA funded research, I understand what that is. I am talking about a license application.

Mr. **Tracy**. It would not have to be. There might be some circumstances where we would.

Mr. **Volkmer**. Mr. Tracy, I am really seriously concerned because I have discussed this yesterday. We discussed it with the IBA people. We discussed it with the EPA people, and I can't find anyone that agrees with you that to maintain confidentiality that you cannot submit data that has been submitted to you for licensing to the ABRAC or the scientific review panel, whatever name you give it.

EPA does it. I talked, in fact, with Dr. Moore, Jack Moore, just yesterday about it. They have no problems with it, and yet you continue to tell us that you have this problem with the confidentiality, and that only people within the marketing division, et cetera, can do this.

Mr. **Tracy**. Only people who are cleared for confidential business information. Now I understand that as Dr. Bentley is developing his new ABRAC, he is planning to provide for review of information which is confidential business information.

You might want to add on.

Dr. **Bentley**. It is mentioned briefly in the testimony. It is in the guidelines. The matter of confidential business information as it relates to the review by the ABRAC will be handled in the manner that has been developed as far as I know it by the NIH RAC. There has been information and review process, and that would be our guideline in the details for it.

Mr. **Volkmer**. Now at the Senate hearing on biotechnology regulation, Dr. Bentley, you described the USDA plan to coordinate the review of genetically engineered products through the Committee on Biotechnology and Agriculture and the ARRC.

Now section 401(h) of H.R. 4452, the legislation presently before these two subcommittees, establish a recombinant DNA review committee within the USDA. How does this compare to the Committee on Biotechnology and Agriculture?

Dr. **Bentley**. Would you repeat the—I want to be sure I get the difference between the CBA—our Committee on Biotechnology and the ABRAC and the ARRC. They are very similar.

Mr. **Volkmer**. And the legislation has proposed to review and what you are proposing for USDA, ABRAC, are very similar.

Dr. **Bentley**. Yes.

Mr. **Volkmer**. So you have no serious problems with what we are proposing in the legislation as far as that committee.

Dr. **Bentley**. As far as my reading of it now, no. And just to add to that, sir, we are referring to the ABRAC review process.

Mr. **Volkmer**. Yes; that is correct.

Mr. **Scheuer**. Congresswoman Jan Meyers of Kansas.

Mrs. **Meyers**. I think that these hearings are interesting, and I am very glad that you are here today. I think there is a great deal of concern about this, not only because of potential danger, but because of possible public cost.

I don't know, Claudine, if you were referring to—the plant that you were referring to was Kudzu? OK. This in Kansas, for instance, has been declared a noxious weed and when a plant is declared a noxious weed in a State, that means that State and county funds are available to help the farmer destroy that weed when it is in his field.

I think there are also Federal funds. In other words, I think that Federal funds flow through the State, and there are county monies available also in this. So it not only is a matter of concern because of danger, but because of public cost. What do you think is your greatest hope for biotechnology? In other words if we are running a danger to the public, there has to be an offsetting benefit that is equal here, and we have seen that there can be real danger and public cost involved, although it wasn't a genetically engineered plant, still Kudzu has caused a great deal of damage.

What is your greatest hope for biotechnology. and what is the greatest achievement thus far with genetically engineered substances?

Dr. **Bentley**. I would like to respond, but before I do I want to be sure that I am limiting my comments. I don't want to take too much time.

One is that I think that one of the great areas that we have in the plant science is to be able to target by gene insertion, gene deletion, changes of this type, a way of introducing resistance to insects and diseases so that we can, in combination with chemicals, perhaps reduce the stress on the environment. That would be one of the major areas I think we will find.

The other thing is to increase the physiological capacity of the plants to utilize nutrients more effectively in water through their root system, for example. So disease control, improving the ability and capacity of plants to deal with stress, which is one of the major things that we do in agriculture research with regard to plants, and thereby increase yields and increase the efficiency of utilization. Those are two.

In the animal area I think there we will be looking at again, perhaps hormonal changes such as the one that is being considered by the bovine growth hormone. This kind of an improvement to aim at improving the efficiency of animals, their ability to cope with disease and stress problems.

Mrs. **Meyers**. Have we had any dramatic success stories?

Dr. **Bentley**. Well, so far there has been more discussion than research. There haven't been completed studies, although the improvements that are reported in the literature for the implementation of the bovine growth hormone that is a dramatic example of what might be. That still hasn't been licensed yet or approved, as I understand it, for general use, but in those areas we have had improvements.

We are talking in terms of putting into plants some resistance to root diseases such as the work that is being considered now by one of the companies of taking a gene or genetic material from an organism and introducing it into the corn plant the capacity for it to deal with not only insects, but to talk about resistance to herbicides. Those are the kinds of things that are exciting.

Mrs. **Meyers**. So we are in the beginning stages of this in this country and all over the world? Are there more success stories in other countries than here? Are they further ahead?

Dr. **Bentley**. It is being developed all over the world. I think the United States is clearly in the lead because of the reservoir basic research that it has had, the number of companies that are trying to move research findings and developments into commercial products. And that is where we are at the moment. And I think that this is being studied in many countries. I happen to have been to a conference on biotechnology in Florida on Tuesday, and there was paper after paper given of people describing things that are being done and the research activities that are being done that show promise for development and application to agriculture.

Mrs. **Meyers**. Thank you very much.

Yes, Mr. Tracy.

Mr. **Tracy**. Just briefly, you asked for any successes. Of course, we don't have very many things out yet. I think if you take the example of the pseudorabies vaccine, which is much safer than any vaccines that had been produced through more traditional methods dealing with an extremely serious and extremely costly disease, I think that is one.

When you start carrying that over into the human health side and view the possible application of the same kind of thing to human diseases which we currently can't control, I think that is one of the most exciting prospects.

Mrs. **Meyers**. I think they are exciting. Yes, Mr. Bentley.

Dr. **Bentley**. May I add just very quickly, I was reminded that this morning's paper gives a report of the approval of one of the interferons for an anticancer treatment that is supposed to have the capacity to function against certain very specified types of cancer. This was done by the FDA. Talk about interferon—well, for me it is about 10 years since people were talking about the potential of interferon and today has the announcement of a product that is now being available to the public for use.

Mrs. **Meyers**. May I ask one more question, Mr. Chairman, and if I am repeating, I am sorry? I am sorry that I was late and didn't hear your testimony and some of the previous questioning.

In terms of regulation, do you think it is most appropriate to do it agency by agency or to have a superagency that as oversight overall all this kind of genetic experimentation?

Dr. **Bentley**. I think it should be agency by agency, but let me ask my colleague to respond.

Mr. **Tracy**. Well, of course we currently have all the various legal authorities under all the assorted acts. We have a group within the USDA. We have got TSCA, FIFRA, et cetera in other parts, and different agencies have different responsibilities. We have been developing, of course, a coordinating mechanism, and we are aware of some cases where there is potential overlap, and we are dealing with those overlaps in the guidelines. We are all waiting for it. So I don't think there is any need to start creating another agency of Government at this point in time.

Mrs. **Meyers**. Thank you, Mr. Chairman.

Mr. **Scheuer**. Thank you very, very much. Thank you to the panel. We benefited from your testimony.

Mr. **Volkmer**. Could I ask the panel a couple more questions?

Mr. **Scheuer**. Well, we are operating under a time constraint. If you have seen our list of witnesses, Chairman Volkmer——

Mr. **Volkmer**. Then may I submit written questions?

Mr. **Scheuer**. I will recognize you for additional questions, but having in mind the fact that we have eight additional witnesses this morning, I would ask you to make your questions brief, and I would request the witnesses to make their answers very brief.

Mr. **Volkmer**. Under what conditions or any conditions are scientists in non-Federal labs required or not required to submit their research plans to you for review on genetically engineered products?

Mr. **Tracy**. When they apply for a license—excuse me, for permit for field tests in the case of plants or in the case of movement of a virus, serum or toxin. That is when they would have to submit their plans, their safety data, et cetera.

Mr. **Volkmer**. Now, if I am genetically engineering a plant in the university lab in conjunction with an industry, with a business, no Federal funding involved, but from any source, and I can conduct my experiment in that lab without any review by USDA, correct?

Dr. BENTLEY. Yes; they would have to work in a university and would be subject to the IBC system. Any university that I know of has a review process involved Institutional Biotechnology Committee——

Mr. VOLKMER. The Biosafety Committee.

Dr. BENTLEY. Yes, and they would review it.

Mr. VOLKMER. But not USDA.

Dr. BENTLEY. But that committee, if they thought there were questions about it, they would then consult with the USDA just as they consult with the NIH right now.

Mr. SCHEUER. If the witness will excuse me, we are here to legislate, and that would be a very Rube Goldberg type of mechanism for us to legislate to protect the public interest. It seems to me that if there is a need to review before release, the appropriate government agency ought to do, and we shouldn't rely on these private voluntary arrangements.

Mr. VOLKMER. That's the first step, and now the second step. I have developed what I think is a safe plant in the laboratory. I'm the investigator, and I have decided that I am going to go out here and I am going to test it on a plot at the university or at my friend's house, anyplace, a small plot, and I'm going to test it. Do I have to apply to the USDA for a permit again? It is all done through private funding.

Mr. TRACY. If there is any prospect that that may be a plant pest or its plant pest status is unknown; yes.

Mr. VOLKMER. All right, now that is where I disagree with you, Mr. Tracy. Under the Plant Pest Act, when do you determine that it is a plant pest?

Mr. TRACY. If it is unknown whether or not it is a plant pest, that is what is covered under our proposed regulations that, again, will be——

Mr. VOLKMER. The present act makes you first determine if it is a plant pest before you can do anything about it. The statute does.

Mr. TRACY. I have an expert on the Plant Pest Act here, if you want. I can have John Wood answer that.

Mr. VOLKMER. In other words, you are telling me that you have statutory authority—and I would like for your counsel to give it to me. I want to see that statutory authority where you could prevent me, by injunction or any other way, by court order, from putting that plant in the ground.

Mr. TRACY. Yes.

Mr. VOLKMER. Because I don't believe it is there.

Mr. SCHEUER. If my colleague will yield, this is exactly the question on which we asked them to provide us a legal memo. I agree with you that that is matter that is very much in doubt in my mind. We would like it to be a legal memo and not a discursive layman's opinion.

Dr. BENTLEY. We will do the very best we can, sir.

Mr. VOLKMER. Now, another important one is when we get into definitions, Mr. Chairman, if I may. If I was going to field test a recombinant DNA organism, animal biological product in farm animals, is that considered a release into the environment?

Mr. Tracy. It would depend. I can't give you a blanket answer.

Mr. Volkmer. When would you make that determination, or would you ever make a determination?

Mr. Tracy. There would have to be an application for movement. If there is a permit for movement for that field test, for instance, we would make a determination at that time. Now, there may have been some research determinations considered before that.

Dr. Bentley. We have to take the assumption here that science driven, and that he would have to consult and utilize the best science available to determine, in the opinion of the reviewers, whether or not there was a problem. Where there is a lot know about organism, you modify these organisms and could prophecy whether or not they would be a problem.

Mr. Volkmer. Do you take the attitude that any inoculation of an animal into an animal is never a release into the environment?

Mr. Tracy. No.

Mr. Volkmer. All right, that helps me there.

Mr. Scheuer. We will resume after about a 12- or 13-minute break to catch this roll call vote. I thank the witnesses very much.

[Recess.]

Mr. Scheuer. We will now hear from Dr. Frank Young, Commissioner of the Food and Drug Administration.

Commissioner, why don't you just chat with us informally for a few minutes, and then I am sure we will have some questions for you.

STATEMENT OF DR. FRANK YOUNG, COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Dr. Young. Thank you, Mr. Chairman. I have no prepared statement, and I really have come to be a resource for you and to help you in understanding in any way you wish the roles of FDA.

FDA has been extensively involved in biotechnology, and has approved in excess of 150 new products for biotechnology, in the last few years. We do this on a product-by-product basis with a particular focus on the product, its mechanism of action and then look at good manufacturing practices and good laboratory practices. By such a method, we are able to, whether it be an animal vaccine—excuse me, an animal biologic or a human biologic or a human drug or some of the other products that we regulate, deal with each of these, focusing on the product first, and approving it on the basis of safety and efficacy.

We, therefore, have tried and true procedures and have been fortunate to, in contrast to some of the others that you asked, have a number of success stories, one of which we had the privilege of announcing yesterday with the licensing of interferon, which is the first time a biologic has been licensed, and we feel the first of many that will see the fruits of the biotechnology revolution supported so extensively by the National Institutes of Health brought to the service of mankind.

Thank you, Mr. Chairman, for the opportunity of coming, and I would be delighted to answer any questions that I might for you.

Mr. Scheuer. Is it your understanding at the present time that the FDA is not covered in the bill that we are scrutinizing, the

Fuqua bill? It is not our intention to cover FDA. It is our intention to cover EPA and USDA. We have no intention of extending jurisdiction to the FDA, and we hope that that is clear in your mind and that you won't have any anxieties on that point or any questions on that point.

Dr. **Young**. We are particularly pleased to hear this. We have not prepared a detailed analysis, nor do I come today with any detailed analysis, but with the hope that the type of product approval mechanism by which FDA has been operating on for these many years will be able to continue, and we are comforted on that, because as a physician, I feel strongly that we need to bring some new medicinal compounds from biotechnology to the American and world population, and that is very comforting, sir.

Mr. **Scheuer**. Congresswoman Claudine Schneider.

Miss **Schneider**. In the evermore competitive world of international commercialization of various drugs, are you of the opinion that there are some reforms taking place within the FDA or a sensitivity to global competition that could help us move such products to the market more rapidly?

Dr. **Young**. I appreciate you asking this question. We have put forward, and I will send a copy to you, an action plan, and the highest priority in FDA is to accelerate with all the safety considerations, the drug approval process. In fact, in the case of interferon, within 1 year that the application was initially filed for the treatment of hairy cell leukemia, and within 6 months from the time of all the data being in place, we approved the application.

We feel that anything longer than 1 year is something that is too long for our new drug approval process. That is particularly important, because with biotechnology, a number of the very important vaccines that could be produced could not be exported to the needy portions of the world without FDA approval unless, as we supported, the export bill was passed. Thus if we had a vaccine for malaria, we would not be able to export this to the very needy people in the world until it was approved, even though we had a good idea it might be safe and effective.

Miss **Schneider**. I am just trying to think. It seems to me that there were examples of some exports that were not permitted in the United States that were permitted in other nations.

Dr. **Young**. That's correct. We have the most stringent export law and are the only nation in the world that a needy nation could not petition and get a yet-to-be-approved drug.

Miss **Schneider**. But yet if some drug is denied by the FDA for usage in the United States, it is my understanding that it is possible for that drug company to sell those drugs in another nation.

Dr. **Young**. Not if it was a U.S. company that did not have its parent in another nation.

Miss **Schneider**. Oh, I see.

Dr. **Young**. If it is a U.S. company, those companies cannot ship, without FDA approval, which goes back to your point that it is imperative that we have the safe and efficient process, but that we not keep applications in line for year, after year, after year.

Miss **Schneider**. Well I very much would be interested in seeing a copy of your new revised action plan.

Dr. **Young**. I would be delighted.

Miss **Schneider**. And seeing as how there are—I really can't ask anymore questions about H.R. 4452 since you are not able to answer anything, but are there any other pieces of information you think this Committee should keep in mind as we listen to the witnesses that will follow you.

Dr. **Young**. There is probably one particular thing that would be of help. I had the privilege of leading, recently, the State Department delegation to the OECD meeting in Paris and negotiating with 24 nations on biotechnology on a safety document, and I shall be providing this to the staff for your consideration.

In that document we identified a very important principle, and that is good industrial large scale practices, which simply states that for organisms that have been used for years and years in fermentation that are of a high degree of safety, that we could set up guidelines in which, in the fields that FDA is involved in, these organisms could be used in a large scale up. For example, the interferon announced yesterday was one that uses a very safe bacterium, Escherichia coli strain K-12 that has been shown to be very safe and not a problem as is the organism that I worked with so many years, Bacillus subtilis. And we brought the principle that said, GILSP, good industrial large-scale practices, are something that we can deal with conventionally with very safe organisms, and then if there is a pathogen that we are dealing with, we have lots of experience with that, and we can add layers of safety there as well.

So this is a 24-nation accord that may be helpful for you in your consideration.

Miss **Schneider**. OK, thank you very much. Thank you, Mr. Chairman.

Mr. **Scheuer**. Chairman Volkmer.

Mr. **Volkmer**. No questions.

Mr. **Scheuer**. OK, thank you very much, Dr. Young.

Dr. **Young**. Thank you very much for the privilege of being with you.

Mr. **Scheuer**. We will now call up the next panel, Mr. Jack Doyle, Director of the Agricultural Resources Project of the Environmental Policy Institute and Dr. David Glass, Director of Patents and Regulatory Affairs of BioTechnica International. We are happy to have you here. Your prepared testimony will be printed in the record in full, so we would ask you to chat with us informally for 6 or 7 minutes, and then after you have both testified, I am sure we will have some questions for you. We will start out with Mr. Jack Doyle.

STATEMENTS OF JACK DOYLE, DIRECTOR, AGRICULTURAL RESOURCES PROJECT, ENVIRONMENTAL POLICY INSTITUTE AND DAVID GLASS, DIRECTOR, PATENTS AND REGULATORY AFFAIRS, BIOTECHNICA INTERNATIONAL

Mr. **Doyle**. Mr. Chairman, we appreciate the opportunity to be here today. We would like to thank you, Mr. Chairman, and the subcommittee for the opportunity to appear here today to testify on the important subjects of biotechnology regulation and the release of genetically altered organisms into the environment.

I would like to paraphrase through my statement, and I would ask permission to submit two other statements for the record, if I could, that I think bear on what we have to consider here today.

[The information follows:]

BIOTECHNOLOGY: REGULATING THE RISKS, DATA GAPS, AND NEEDED RESEARCH

- JACK DOYLE*

As we sit here in this room today, precisely at this hour, the House Science and Technology Subcommittee on Investigations and Oversight is convening a hearing on the matter of an illegal environmental release of genetically-altered bacteria by a company named Advanced Genetic Sciences. The release occurred over one year ago, and AGS never bothered to tell anyone, least of all EPA, even though it was then involved with that agency seeking a permit to field test the very same bacterium. And this is the same firm that failed to tell local officials in Monterey County, California that it was planning to conduct the field test that EPA approved in that county. I'd say the industry has a credibility problem today, and will continue to have, if it keeps operating like that.

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*Jack Doyle is Director of the Agricultural Resources Project for the Environmental Policy Institute of Washington, D.C. His new book on the subject of agricultural biotechnology, Altered Harvest (Viking), is available in bookstores. These remarks were presented at the Institute for Alternative Agriculture Symposium, "Implications of Biotechnology for Sustainable Farming Systems", held in Washington, March 4, 1986.

Last Friday, the Environmental Policy Institute (EPI) signed a letter with the Natural Resources Defense Council of New York and the Committee for Responsible Genetics in Boston, calling on EPA Adminstrator Lee Thomas to revoke the AGS permit pending a full investigation and public discussion about how EPA is making its decisions in this area. EPA and the public have been deceived in this instance, the public trust has been violated, and the public, together with Congress, would do well to look closely at this situation to insure timely and thorough regulation of this new industry in the future.

I've been invited hear to talk about biotechnology regulation, as well as the subjects of risk, regulation, data gaps, and needed research. Let me briefly summarize these topics by saying -- First, there are risks. Second, there are also data gaps. Third, there is much needed research. And finally, as we've seen all too clearly in the AGS incident, there is no effective regulation.

I believe biotechnology and genetic engineering will present risks both to the economy and the environment because of what we don't know about the organisms being released, and the environments into which they will be released.

When considering the release of genetically-altered organisms into the environment, there are 5 general questions that we need to ask to determine whether the release might have some negative or unforseen impact. These five questions -- generally credited to Cornell microbiologist Dr. Martin Alexander -- are as follows:

1.) Will the organisms survive?
2.) Will they multiply?
3.) Will they transfer their inserted genetic changes to other species?
4.) Will they be transported or disseminated to new sites?
5.) Will they have a deleterious effect?

The ability to predict what might happen with genetically engineered organisms in the environment will have to build on what is known about the ecology of existing organisms. But the trouble is, we have not collected much ecological information on existing organisms.

Today, in the agricultural environment, there are -- (and these figures may be very laow) -- at least 160 species of bacteria, 250 kinds of viruses, 8,000 species of insects, and 2,000 species of weeds. But how much do we really know about these and other yet unidentified species?

Some scientists estimate that as many as 80% of our soil microbes have yet to be cultured, and perhaps as many as 90% don't have names. Of those that are named, we don't know much about their relationship with other microbes.

Many ecologists agree that little is known about the dynamics of how organisms such as these establish themselves, or why some species multiply in nature and others do not, or what attributes make some organisms good at dissemination and others poor.

The Cornell Study

In February 1985, the Cornell University Ecosystems Research Center issued one of the first comprehensive overviews of what was possible and what was lacking in the way of assessing the environmental risks of new biotechnology products. The findings of that report are fairly astonishing -- especially with regard to revelaing how little we know about how bacteria survive, grow and are dispersed in the environment.

Let's look at some of the Cornell findings with regard to the 5 questions I asked earlier.

Survival. The Cornell study noted, "Review of the literature on bacterial survival indicates considerable contradictory information ". The report also notes that the factors favoring bacterial growth generally, "are not well known".

Dispersal. What about the dispersal of organisms in air, water, and by animals and insects? The report notes that many such movements can be modeled by computer and predicted to some degree. However, the report also adds that "long-distance dispersal occurs unpredictably, adding uncertainty to any fate analyses".

Genetic Transfer. The Cornell report says that the ability of microbes to transfer genetic information between species, through at least 3 mechansims, "add further uncertainty to the prediction of responses".

These are only a few of the observations raised in the Cornell study, and there are other studies citing some of the same data gaps and shortcomings. And there are other issues as well.

Vectors. Today in gene splicing, our scientists are using viruses and bacterial plasmids to ferry new genes into target organisms. Some scientists believe that these vectors, as they are called, can also rearrange existing genes in new ways, leading to unanticipated results.

And there are also certain fallacies floating around about genetic engineering being exact, or only comprising the addition of one or a few highly-characterized genes that are well understood. In some cases, that may be true. Yet in other instances, whole blocks of uncharacterized genes are also being moved around, and in some cases, entirely unrelated genomes are being combined through a variety of biotechnological procedures.

But let me provide you with a little context here -- as to why better data and careful ecological review are needed.

What we have the capability of doing with biotechnology is synthetically or artifically increasing the number of mutations in biological systems. And here, I am again borrowing heavily from the work of Dr. Martin Alexander of Cornell.

In nature, the occurrence of a single mutation in a plant or a microbe is a relatively rare event, perhaps one in a million staatistically. A second mutation, arising from a successful population of the first mutant -- called a double mutation -- is even rarer, and perhaps unlikely in nature, put a probability of one in a billion. But all that changes when science begins purposely selecting organisms for their mutations in the laboratory with the help of various bioengineering and recombinant techniques.

What may have been a rare event in a natural environment with competing organisms and other biological pressures, can in the laboratory become a predictable, controllable, and repeatable occurrence. According to Dr. Alexander, double, triple, and quadruple mutants can be made to appear with ease. Bio-engineering, in other words, can increase the mutational frequency of organisms far beyond that of the natural environment. And such laboratory-bred mutants may express characteristics -- valuable to commerce but possibly harmful to the environment -- that may have never been expressed in nature because of the odds against the survival of new organisms

Now, this is important because some evolutionary biologists (Lenski, Levin) have noted that once a recombinant population is established, it can be expected to evolve in ways beneficial to its own survival, and that could increase its undesirable effects as well, if it turned out to have those. And it is worth remembering here that there is no recall of living organisms.

So, it behooves us to do careful ecological assessments beforehand. But that capability doesn't seem to be available.

Only since 1983 have our government and scientific institutions begun to think in-depth about what genetically-alterd organisms might do in the environment outside the laboratory. Prior to this time, the real focus of biotechnology and gene-splicing was inside the laboratory. In fact, early versions of the NIH recombinant DNA guidelines flatly prohibited the deliberate environmental release of any genetically altered organism. So let's look at some of this recent history.

Risk Assessment & Predictive Capabilities. In June 1983, EPA Assistant Administrator for Pesticides and Toxic Substances, Don Clay, testified in Congress that "There are almost no accepted metodologies for evaluating the safety of genetically-engineered products." And Clay added that the needed techniques and methologies were then "several years away".

But by 1985, we seemed no closer to answering this need. The Cornell study noted, for example,that "Deficiencies in methodlogies, both for biological effects assessment and exposure assessment, make quantitative risk assessment difficult or impossible at presnt. Development of appropriate methods and a data base from which to derive criteria are needed".

In its conclusions, the Cornell study explained: "Methods for predicting the liklihood of survivial and proliferation of a given organism in the environment are crude... Methods are available for assessing some potential effects, but there are many deficiencies in current knowledge and theory. Generally, we lack any true data base against which to compare test results or predict environmental consequences".

As for field testing, the Cornell study had this to say:

> As an alternative to,or precursor of, field testing, the use of microcosoms coupled with matematical models appears to provide a basis for testing to provide assessment of biotechnology products in an evironmentally safe manner. Additional and specific safety assurances are needed before field testing can be undertaken.

It's not surprising to find that we lack the needed ecological data and the predictive methodologies to evaluate what might happen with genetically altered organisms turned loose in the environment.

Only since 1983 have our govenrment and scientific institutions begun to think in-depth about what genetically-altered organisms might do in the environment outside the laboratory. Prior to this time, the real focus of biotechnology and gene splicing was inside the laboratory.

Only as recently as June 1985 did molecular biologists and ecologists, meeting for the first time, begin to start a scientific dialogue on the issue of environmnental release. In Philadelphia last summer they met specifically on the question of "Engineered Organisms in the Environment: Scientific Issues". Not a whole lot of agreement was reached at that meeting, but it did serve to stimulate more involvment in this question from ecologists

Some of the first ecologists to raise questions on the issue of deliberate release into the environment were those who testified at the June 1983 hearings in the House. However, one thing is clear in this brief history of inter-scientific debate on genetically-altered organisms: as more and more ecologists have been drawn into the fray, more and more questions have begun to be asked, and more and more uncertainty and data gaps have begun to appear.

The Direction At The Top

One of the reasons, in my view, why we are no closer to resolving the data gaps and predictive shortcomings which currently plague biotechnology, is in part, due to the way the Reagan Administration has conducted its science. Take the former head of the White House science office, George Keyworth, who left his mark on the government's science process as it operates today. In being an unabashed supporter of Star Wars, Keyworth made plain his views on the way the best science gets to the White House. Keyworth believed that science policy should start at the top -- at the White House -- and work its way down to the scientific community as something to be supported, rather than percolate up to the White House from the best scientific minds in the nation. Some of that philosophy is still at work in OSTP's effort to "coordinate" biotechnology science and regulation

In fact, if you look at the history of what the Reagan Administration has done in the area of biotechnology -- and here I'm talking about the State Department, the Commerce Department, OSTP, OMB and the Domestic Council -- you find much more activity and concern for furthering and enhancing commercial investment than you do for protecting public health and safety. Let me give you a few examples, just since 1982.

In October 1982, the White House Office of Science and Technology Policy (OSTP) commissions a study and a working group on U.S. biotechnology competitiveness, to be coordinated by the State Department. In April 1983, this government working group meets with representatives of 9 biotechnology compnanies and corporations in the Virginia countryside to finalize the reports recommendations. The final report suggests changes in patent law, export controls, tax policy, and anti-trust law to allow biotechnology to flourish. "More restrictive controls", as regulations are called in the report, are not warranted.

By August 1983, however, an interesting development occurs. EPA asserts at a Congressional hearing that it will regulate genetically-altered products under the Toxic Substances Control

Act. Very few people were expecting that, it seems, and no one at the time really knew what to make of it.

Then in September, NIH is sued by Jeremy Rifkin for approving the "ice-minus" bacterium without doing an environmental impact statement consistent with the provisions of the National Environmental Policy Act (NEPA). No injunction or restraining orders are issued at the time since the Univeristy of California scientist involved decides to postpone his test until the following Spring. The lawsuit raises the visibility of the issue, and the question of regulating field tests.

In the meantime, OMB is starting to become involved in the issue. One OMB official objects strongly to EPA's initiative to regulate. In a March 12th, 1984 memo to the Cabinet Council on Economic Affairs, Christopher DeMuth argues that the Council, not EPA, should decide how to regulate biotechnology. In the memo, DeMuth refers to EPA's proposal as a "gambit", and voices concern that too much regulation would hurt biotechnology companies, which he viewed as "extraordinarily innovative" but "unusually sensitive to regulatory costs and delays".

In his list of regulatory options, and alternatives to the EPA view, DeMuth listed doing nothing, asking the National Academy of Sciences to study the issue, and keeping the status quo in tact under NIH, among others. (One account of OMB's involvement in this matter charged that OMB and DeMuth were under pressure from the Daprtment of Commerce and Secreatary of Commerce, Malcolm Baldridge, who was concerned that EPA regulation would hinder U.S. biotechnology companies in competition with Japan)

All of this internal turf-fighting led to the demise of EPA's, and William Ruckelshaus', lead on the biotechnology question within the Domestic Council. By April 30, 1984, the Working Group on Biotechnology of the Cabinet Council on Natural Resources has been created, under the chairmanship of OSTP's George Keyworth.

By May 1984, the National Academy of Sciences' Board on Agriculture and Board on Basic Biology -- to their credit-- formally floated a proposal to examine the data and scientific problems associated with doing environmental and public health risk assessments for genetically-altered organisms. This study was to be funded by interested federal agencies. But OSTP, worried about the delay such a study might bring to the

Administration's plan for regulation, put the word out that the study should not be funded, and that's where it remains to this day.

A few congressional hearings were held in September and December of 1984, and on December 31st, 1984, the Administration issued its proposed "coordinated framework" for regulating biotechnology, which amounted to a patchwork quilt of existing authorities from USDA, EPA, FDA and NIH. Politically, the idea of this exercise was to keep Congress from writing new law. Yet the OSTP framework was entirely inadequate, and featured glaring contradictions in approach even among the three agencies that tried to "coordinate". Today, a new mechanism has been created, called the Biotechnology Science Coordinating Committee (BSCC), whose authority to do anything more than advice existing agencies on matters of biotechnology science and needed research, is questionable. And we are still waiting for "Son of OSTP framework", to be published sometime in May of this year, if we're lucky.

Today, the regulatory situation remains unclear, with several bills now being drafted in Congress. What we have had so far is regulation by litigation rather than by thoughtful statute. In my view, it's time for Congress to really exercise some leadership on this issue, as well as consider some fresh approaches.

Let me turn now, briefly, to research needs, and then I'll sit down.

Needed Research

First, we need to fill-in our data base where gaps now exist in identifying species of weeds, viruses, bacteria, fungi, etc.

Second, we need to do a whole lot more work in ecology; in systematizing data on ecological relationships, and particulalry for those organisms likely to be the targets of genetic engineering.

Third, we need to build in an assessment function that works side-by-side with the research function.

Fourth, we also desparately need an alternatives mentality built into the research process so that our farmers and agricultural system are not bowled over by one new type of biotechnology product line or another.

And finally, let me suggest something that might be considered a little radical, if not improvident in these times of Gramn-Rudman fever. As one way of rejuvenating the funding interest in the land-grant system -- and in a way that may even interest Jamie Whitten (even he needs to broaden his political base) -- might be to establish a program for interdisciplinary ecological research centers focused on the data gaps and assessment needs now confronting the biotechnology industry in the area of environmental release. While such a program -- perhaps modestly funded as a pilot program in the first year or two -- may or may not interest a large number of researchers presently in the system, the real aim would be to interest graduate and undergraduate students in the field of agricultural/ecological systems, and biotechnology effects assessment in the broadest sense of that term.

Thank you.

ENVIRONMENTAL POLICY INSTITUTE

TESTIMONY OF JACK DOYLE
DIRECTOR, AGRICULTURAL RESOURCES PROJECT
ENVIRONMENTAL POLICY INSTITUTE

BEFORE THE SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT OF THE
U.S. HOUSE OF REPRESENTATIVES COMMITTEE ON SCIENCE & TECHNOLOGY

THE REGULATION OF COMMERCIAL BIOTECHNOLOGY

17 APRIL 1985

Mr. Chairman, Members of the Subcommittee:

My name is Jack Doyle, I am Director of the Agricultural Resources Project for the Environmental Policy Institute (EPI). EPI is a non-profit, public interest organization engaged in research, public education, litigation and lobbying. Our researchers and lobbyists work on energy, environmental and natural resource policy at the local, national, and international levels. We appreciate the opportunity to appear before this subcommittee today to share our views on the very important topic of regulating biotechnology and the corollary issue of releasing genetically altered substances into the environment. We commend the chairman, members, and staff of this subcommittee for holding

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these exploratory hearings, and trust that they will be followed by others examing how these new biological and genetic technologies will affect our society, economy, and environment.

For the last three years, I have been working on a book about agricultural biotechnology, and in the course of researching this book, I have visited with numerous scientists and businessmen. There is no doubt in my mind that we have a revolutionary tool in our hands. While there is much promise for agriculture and the environment with the use of new genetic technologies, there are also some clear reasons for concern and caution. How the federal government goes about regulating this technology may well determine whether this industry advances smoothly and safely, or instead, is hampered by conflicting jurisdictions and gray areas that invite a public health or environmental calamity.

Two days ago we submitted our comments on the proposed OSTP regulatory framework for biotechnology. At first blush, this 51-page Federal Register notice is an impressive document, with an elaborate matrix of proposed regulatory authorities. And indeed, we commend Dr. Bulkley, her colleagues, and the participating federal agencies for coming this far.

Yet, we believe this document is, first of all, premature, and secondly, is inadequate and incomplete. It is premature because the federal government is attempting to devise a regulatory framework before it has an adequate scientific review capability in place -- and this is especially true in the area of the deliberate release of genetically-altered organisms into the environment. Secondly, this proposed framework is inadequate and incomplete for a number of reasons -- including questions concerning legal authority, omissions of statements from key agencies, and lack of a clear public participation program -- all of which are outlined in the detailed comments we submitted to OSTP (and we ask that this document be printed in the hearing record).

But first, consider some recent history connected with biotechnology and genetics in this country; particularly the history of the federal establishment's fledgling attempt to come to grips with the deliberate release issue; a history punctuated by procedural mistakes such as NIH's procedural blunder on its NEPA responsibilities which led to litigation; and on-again, off-again federal agency initiatives, such as EPA's lone attempt in 1983 to claim regulatory responsibility under FIFRA and TSCA which was then halted by OMB a year later. The problem now, is that we have agencies such as Commerce and the State Department pulling for our international lead in biotechnology; agencies such as USDA emphasizing higher efficiencies and more agricultural production through biotechnology; FDA advancing products for the pharmaceutical industry; and virtually no one -- save a few souls at EPA -- looking out for the public health and safety.

Add to this the almost monthly addition of some new federal biotechnology program, and new assessment programs, such as

USDA's endorsement yesterday of a proposed National Biological Impact Assessment Program (which I don't believe was included in the OSTP framework), and you have an increasing sense of confused responsibility in the federal establishment that is bewildering and almost defies description. But the real core issue here is the science.

Consider the matter of making scientific predictions about what genetically-altered microbes will or will not do in the environment.

Less than two years ago, this subcommittee heard testimony from EPA, which then asserted it had authority to regulate certain products of biotechnology under FIFRA and TSCA. Yet, even then EPA's Assistant Administrator Don Clay noted, "There are almost no accepted methodologies for evaluating the safety of genetically-engineered products," adding that the risk assessment tools and data used for chemical substances could not apply in the case of living organisms. Clay explained that the EPA needed to develop methodologies to evaluate environmental fate, human exposure, and the potential environmental and health hazards of genetically-engineered organisms, but that such tests were "still several years away." How much closer are we today?

Since Don Clay made these statements, there have been two other congressional hearings on the deliberate release issue, and independent scientists testifying at those hearings, and others filing statements in connection with litigation, all of whom have raised questions about our ability to predict what might happen in the environment with genetically-altered organisms.

It is our belief, that based on the scientific record and agency opinions so far, that we have an uncertain situation with regard to adequately predicting what will happen ecologically with genetically-altered organisms once they are released into the environment. We need more information about risk, and how risk assessment relates to regulation, before we move ahead.

Usually, when the federal government is faced with this kind of situation, it asks the National Academy of Sciences to conduct a study before taking an action. And indeed, in this case, the Academy itself saw the need for an examination of the environmental and public health implications of genetic engineering last year, and drafted a proposal to conduct such a study. However that study has run into difficulty obtaining funding since OSTP initiated its Cabinet Council Working Group on Biotechnology in April 1984 and proposed its framework in December 1984. In fact, sources I have contacted in the Academy have told me specifically that OSTP does not want the Academy to conduct this study because some people there do not want to broaden the public debate on this issue. Yet in light of the incompleteness and inadequacy of the proposed OSTP framework, and its political history, we believe that a comprehensive and objective study by the National Academy of Sciences on this subject is essential before the federal government or Congress move any further toward establishing biotechnology regulation. Therefore, we ask this subcommittee, the full committee, and other appropriate committees in Congress to intercede at this time to insure that the existing NAS proposal is funded and undertaken immediately. The details concerning the Academy's original proposal are included in our OSTP comments as well as our suggestions for improving the scientific neutrality needed for credibility and public confidence in such a study.

Our purpose in making this request today is not to block the progress of this new technology -- which we fell has some very promising potential for reducing pesticide use in agriculture -- but to insure that as a nation we take some time now to carefully evaluate where we are with our scientific capabilities before we begin approving thousands of products for thousands of locations that could have very lasting genetic changes that will be difficult if not impossible to recall.

The recent history of scientists raising concerns about the potential ecological impacts and uncertainties of releasing genetically-altered organisms, plus the National Academy's own proposal which also discusses this issue, underscores the need for our nation's highest science body to study this matter comprehensively rather than leaving it fall to ad hoc White House working groups or individual agency initiatives.

Let me explore with you here just one reason why we believe the predictive science base -- a predictive ecology beyond what we have today -- is so important. Today, what we have the capability of doing with biotechnology is synthetically or artificially increasing the number of mutations in biological systems. And here I am borrowing heavily from the work of Dr. Martin Alexander of Cornell.

In nature, the occurrence of a single mutation in a plant or a microbe is a relatively rare event, perhaps one in a million statistically. A second mutation, arising from a successful population of the first mutant -- called a double mutation -- is even rarer, and perhaps unlikely in nature, put at a probability of one in a billion. But all that changes when science begins purposely selecting organisms for their mutations in the laboratory, using the high-speed techniques of biotechnology. What may have been a rare event in a natural environment with competing organisms and other biological pressures can in the laboratory become a predictable, controllable, and repeatable occurrence. According to Dr. Alexander, double, triple, and quadruple mutants can be made to appear with ease. Bio-engineering, in other words, can increase the mutational frequency of organisms far beyond that of the natural environment. And such laboratory-bred mutants may express valuable characteristics -- commercial or otherwise -- that may never have been expressed in nature because of the odds against the survival of new organisms. Again, according to Dr. Alexander, "we can create new genotypes which do have survival value even if the potential for the expression of that survival value would not ordinarily have occurred." But what happens when such laboratory-based mutations are fashioned for use in the outside environment and released there? No one seems to know for sure.

There has been little scientific study or data collection on how existing non-engineered organisms generally behave in nature, let alone understanding of genetically-altered ones. For example, little attention has been given to the dynamics of how organisms establish themselves, or why some species multiply in nature and others do not, or what attributes make some organisms good at moving over large distances while others are poor at dissemination.

Some of this information does exist, but not always for the organisms of most interest to genetic engineers, or not in ways that are useful when dealing with genetically-altered organisms. The point is, we do not have a good basis of scientific information that allows us to make reasonably sound predictions about what might happen.

Unfortunately, we seem to have a history of discovering risk only after a calamity, or after substantial amounts of capital and production plant have been committed; after political positions have been taken and courses of action set in motion.

A second reason for our concern in the ecological, as well as economic area, is how much we still do not know about the genetic realm. Consider, for example, some recent genetic history:

- In 1951, to the disbelief of her scientific peers, Nobel prize winner Barbara McClintock first offered her discovery of "jumping genes." McClintock discovered that the genes on chromosomes -- once believed to be stationary and therefore predictable in the genetic characteristics they controlled -- could move or "jump" from one chromosome strand to another, thus affecting changes in the expression of certain traits. What is most interesting and instructive about the McClintock episode is that it took nearly 20 years for the scientific community to finally accept her discovery.
- In the early 1960s, after several dysentery epidemics had broken out in Japan because some bacteria were beginning to become resistant to antibiotics such as streptomycin and tetracycline, scientists learned that tiny bits of DNA -- later known as plasmids -- which resided outside of the chromosome, could move freely among their own kind and even others of another species to communicate antibiotic resistant genes. That discovery caused a fundamental reevaluation of evolutionary theory, as well as the feeding of antibiotics to livestock on a routine basis.
- In 1970, plant scientists generally thought that the genetic traits that determine disease resistance and/or susceptibility in crops were contained in the nucleus of the cell. But after the Southern Corn Blight wiped out 15% of the nation's corn crop in 1970, they discovered otherwise. They discovered that cytoplasm -- the liquid material contained in every cell -- also had something to do with the genetics of disease reaction. That was new information.
- In 1983 we first began to hear the term "promiscuous DNA," meaning that DNA sequences could move about within the confines of the cell, in this case between chloroplasts and mitochondria. Scientists studying this transfer activity at Duke University and the Carnegie Institution concluded that this was not a rare event, but a "general

phenomenon." Before this discovery, scientists had assumed that intra-cellular organelles like chloroplasts and mitochondria were independent of each other. Now they know differently, but how the DNA gets from one organelle to another is still a mystery.

- And only a few weeks ago was it revealed that researchers in the U.S., Japan and Europe studying Paramecium and one kind of bacterium, contain a DNA segment that sends a different protein code than what was standardly accepted as a universal truth, again changing the thinking about hard-and-fast rules concerning the genetic code as well as evolution.

Another concern of ours which relates directly to the question of the need for sound scientific information and regulation, is what the public is being told about this new technology. We hear much from the biotechnology industry and federal agencies such as USDA about how biotechnology is nothing new; about how it is only an extension of classical genetics. Yet while this technology can be described as an extension of the genetics of the past, it is a new dimension of genetic power; a power that can magnify in nature certain abilities that have taken thousands of years to evolve; a power that can now cross species barriers and design truly super breeds of plants, livestock and microbes. These are biologically-altered introductions of a new order that could well have super impacts of one kind or another -- of both the economic and ecological variety.

And on this point, it is interesting to note that the current debate over regulating biotechnology has focused almost exclusively on the potential environmental or ecological impacts. Yet an equally important reason for over-seeing the release of new genetically-altered products is the potential for substantial *economic* impact. The 1970-71 Corn Blight, which was the result of genetic alteration in the cytoplasm, caused a $1 billion loss. In my book, that's a very substantial economic impact. And I'm not sure we have learned the lesson of the Corn Blight yet.

I think we have a lot to learn from history, and in our OSTP comments we propose several in-depth case studies which evaluate our handling of crises such as the Corn Blight, the Med fly outbreaks, the rise of antibiotic resistance, Pennsylvania's poultry virus, and Florida's citrus canker. How have genetics played a role in each of these crises?

Today we read of a *salmonella*-in-milk production problem in the Midwest, a health problem now exacerbated by *salmonella* resistant to antibiotics. I think this is a vivid example of hwo mistakes and accidents can be magnified and compounded by what goes on in the genetic realm, and how we should approach that realm with care.

# # #

In the OSTP proposal, there is a great concern expressed for maintaining the U.S. lead in biotechnology; great concern for our "international competitiveness," as well as an eagerness for the "international harmonization" of biotechnology regulations. We hope, however, that the Reagan Administration's enthusiasm for the industry's international position does not result in our nation taking the lead for a lowest-common-denominator type regulation, which we believe would invite a "biotechnological Bhopal" that would surely damage the progress of this new industry as well as our credibility in the world community.

For these reasons, and others already mentioned, it is important that we pause now and have some rigorous scientific analysis of the biotechnology question, and particularly the release of genetically-altered organisms into the environment.

Thank you for allowing us to express our views here today.

Mr. DOYLE. Mr. Chairman, I would like to begin by making three points which I think summarize the position of the Environmental Policy Institute on these topics. First, I think with the release of genetically altered organisms we are dealing with a considerable amount of scientific uncertainty, as you heard from certain panels yesterday, in terms of being able to predict what will happen with the release of genetically altered organisms into the environment, ecological as well as economic impacts. We'd like a good data base. We don't have a good assessment capability.

Second, I think that the existing interim regulatory system for biotechnology, which has been going on for nearly 3 years now, ever since EPA came up to the Hill in June 1983 and asserted that they had jurisdiction under TSCA, so we have been dealing with this interim situation for 3 years now. I think over that period of time, that interim system for regulating biotechnology has failed to instill confidence in the Government's ability to regulate, as well as inform a broader public of what the issues are here.

Third, I think there is a growing sense of confusion, and we find confusion and mistrust in both the administration and the industry brought on by a chain of incidents that I think were adequately documented by Congressman Volkmer in his statement, which we would like to associate ourselves with. We think that was a good accounting of what has happened in this situation over the last couple of years. I mean we have seen incidents of data falsification, improper approvals, lack of notification to local officials. Federal officials in some cases haven't been notified what other Federal agencies are doing.

We have seen intra- and inter-agency turf fighting over jurisdiction, missed guidelines with the latest revision of the guidelines, key personnel changes, philosophical shifts in the administration's working group on biotechnology, and generally a lack of leadership. Now this is not to say that there haven't been some bright lights in what has gone on in the administration. I would say that the recent action of EPA in stepping back from the Monsanto application, I think that was a very good action on the part of EPA, and we commend that move on the part of the Environmental Protection Agency.

We believe that it is really important that Congress take the initiative here. I mean if the administration has had the ball for 3 years now and haven't really delivered on the clear regulatory pathway, I think it is time for Congress to act, and I think it is important to note that we have had a series of hearings. We have had some useful studies from OTA, from GAO, but no congressional committee has yet really taken a systematic review of the panoply of laws that are supposed to be used for regulating biotechnology. Congress has deferred to the administration to make this judgment. I think it is time for Congress to step in and take a very concerted look at some of the legal jurisdictions.

Historically, the administration has been the sole actor and Congress needs now to move, and we would like to commend these subcommittees, as well as the initiative with H.R. 4452 as a step in that direction.

I would like to focus on two areas, if I could, to first make some general comments about what the administration has been doing, and second to look a little bit in detail at USDA. If you look historically at how the administration's package developed, I think initially it grew out of an exercise out of the Office of Science and Technology Policy and OMB to try to, we believe, preempt EPA from taking regulatory authority on this issue, and at the same time it took the ball away from Congress or preempted Congress from getting into the action. But the sole focus of this activity so far has been more, at times, overly concerned, in our view, with international competitiveness and putting public health and safety on a back burner.

Now, further if you look at the creation of the BSCC, we are not sure that the BSCC is anything more than what the National Science Foundation already does in terms of coordinating science policy. It was created for the express purpose of science coordination under its latest rubric, but we think the real mission of the BSCC, as evidence by what we here are coming in terms of definition changes, is to have a very determined impact what will and will not be regulated by way of definition. One of our concerns there are the exemptions, these so-called exemptions or lesser product review involved where organisms with genes deleted—we are hearing that organisms with genes deleted would be exempted, and we think there is a problem there.

One biologist from MIT, Jonathan King, has stated, "It is a medieval scientific view that a deletion is automatically less risky." Other biochemists, Liebe Cavalieri, from Cornell, also raised concerns. Here he was talking about ice minus. "It is well-established that altering of a genotype, even limited to the change of a single gene, alters the metabolism of the bacteria," in this case the pseudomonas seringae that is being considered by AGS.

Looking at what BSCC has proposed and what we are hearing in terms of definitional changes, that dismays us greatly because we are at such an early stage with this technology that we should be taking more caution rather than less, and it is very important to have a careful look at what the administration is proposing there.

In my statement I have some details about USDA in terms of their statutes and the existing authority that they have and the inadequacies of those laws, and I won't go through listing them. They are in the statement for you to read, as well as documentation of those particular points. But I would like to summarize by saying that the USDA statutes, with the possible exception of the Virus Serum Toxin Act, these are basically after-the-fact registrars of what has already happened, essentially a list of pests, contagions and infectious agents that have already expressed themselves on the landscape offering remedies for a future that deals with those agents and not necessarily new mutants or the problem of genetic exchange or the creation of potentially vulnerable situations in agriculture and other areas of the environment that may result from the use of genetically altered organisms.

The USDA statutes, rather than being anticipatory and environmental in orientation to prevent problems, the USDA statutes are more or less after-the-fact enumerators and catalogs of what has already occurred. In addition, I think it is very important to look at the pesticide experience at USDA. If we recall, FIFRA was originally administered by USDA, and over the course of nearly 20 years, there is a record which is documented in my statement of how USDA mishandled the use of regulating pesticides until 1970 when EPA was created and that jurisdiction shifted.

I think as a society we are still paying for USDA's early mistakes in pesticides. We have legacy of 45,000 pesticides, and the reregistration fight over FIFRA right now, I think, is in part because of the problem historically we have had with USDA's jurisdiction.

Second, there have been a few environmental initiatives created in USDA. For example, in 1978 there was an office of environmental quality created, and at that time we even had an assistant secretary for natural resources in the environment. But by 1981 all of that was dismantled and were reorganized to the farther parts of the department. Then we have the incidents of USDA's mishandling of the pseudorabies vaccine, GAO's report on their researchers view environmental risks with their experiments, all of this is to say that USDA is not an agency with an environmental mission. They are not primarily an agency that is out to protect public health and safety and the environment, and USDA is not alone in that category. I would place other agencies involved in the administration review process from the State Department, Commerce, and BSCC itself as not having an environmental mission.

Now, the reason I am focusing on this is because we are talking mostly about the release of genetically altered organisms into the environment, so I think that the environmental focus is a very important one, because we are not only talking about agricultural products here, we are talking about the whole panoply of environmental media—air and soil, fields, and forests. We are talking about genetically altered fish, oceans being affected, estuaries, the whole range of environmental media will be affected by new organisms that will be coming not one at a time, but very rapidly in hundreds of submissions for everything from toxic waste cleanup to hard rock mining, forestry use, et cetera.

So the environmental science and the environmental protection aspects are very important, and we find in our survey of the agencies that really EPA is the only Federal agency that has a clear mission for environmental review and protection, and we would like to propose a biotechnology science board that would be housed in EPA or on a level with the administrator that would become the traffic cop for all permit applications for environmental release of genetically altered organism.

Now, this is not necessarily a new idea. This is something that was proposed by the administration in its first framework, in a different context, but we think it deserves consideration in any legislation that would work its way through the Congress. We think that the focus at EPA is a very important one, and we urge the committee to consider it.

In terms of the legislation, H.R. 4452, while there are really some very nice provisions, very important provisions in H.R. 4452, particularly the tiered permit approach and the public notification provisions. We would suggest that the committee might want to consider extensive revisions, given some of the testimony that you have heard in the past couple of days, or even starting with a new bill and just looking at a broader range of options.

We are not prepared at this time to support the bill, although we do agree that legislation is needed to clarify the situation and to assure the public safeguards and protection will be in place. If I might say one further thing, I think as the recent citizen protests have evidenced themselves in places where the field tests are being planned for—in Monterey County, St. Charles County, MO; and Tulelake, CA, we are finding—I think this is one expression of the fact that the administration, and to some extent the companies, haven't really reached out and involved the broader public in this technology, and it is really important to do that, and I would emphasize the importance of that in legislation and incorporating strong citizen participation provisions in this legislation.

Now, I am not alone in suggesting this. I recall last year at the National Academy of Sciences a former EPA administrator, William Ruckleshaus, told his listeners in a speech that with public participation in biotechnology, you have to go beyond just the Federal Register. It is not enough to do the public notices through the Federal Register. You need to have a broader public participation program. And if I may quote, finally, from Ruckelshaus at that forum, he said, "If the Government doesn't do its job," he said, "It is unlikely that the United States will stay ahead either in the research or the commercialization of this new technology."

And he added that there were two ways in which the Government might not do its job right.

> One is that the government would do too much; there would be very heavy-handed regulation, needless time-delaying, red tape, nitpicking, an unwillingness on the part of government ever to make a decision. if there is too much regulation, we could stifle this emerging technology. On the other side, that could happen also if there is too little regulation, or if it is unwise or sloppy or not open. That could just as certainly doom our efforts to take advantage of our current lead.

So with that, I would close, and just to underscore the importance, I think, of involving the broader public here and thinking about those kinds of provisions in the legislation. Thank you.

[The prepared statement of Mr. Doyle follows:]

ENVIRONMENTAL POLICY INSTITUTE

TESTIMONY OF JACK DOYLE*
DIRECTOR, AGRICULTURAL RESOURCES PROJECT
ENVIRONMENTAL POLICY INSTITUTE

BEFORE THE HOUSE SCIENCE & TECHNOLOGY SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURE, RESEARCH AND ENVIRONMENT, AND THE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY

FEDERAL REGULATION OF GENETICALLY ENGINEERED ORGANISMS DESTINED FOR COMMERCIAL USES IN THE ENVIRONMENT

5 JUNE 1986

Mr. Chairman, Members of the Subcommittees:

I am Jack Doyle, Director of the Agricultural Resources Project for the Environmental Policy Institute (EPI). EPI is a non-profit, public interest organization engaged in research, public education, litigation and lobbying. Our researchers and lobbyists work on energy, environmental and natural resource issues at the local, national and international levels. We appreciate the opportunity to appear here today to share our views on the very important subjects of biotechnology regulation and the environmental release of genetically-altered organisms.

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*unedited version; revisions and extensions may follow

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Today I would like to make some general comments on the overall regulatory situation and pending proposals, as well as some specific comments and suggestions on what course might be taken. But I would like to begin by making three points which I think summarize the concerns of the Environmental Policy Institute.

First, with the release of genetically-altered organisms into the environment, we are dealing with a considerable amount of scientific uncertainty in terms of what kinds of ecological and economic to expect; we lack a good data base on the organisms that will be released and we lack proven assessment capabilities. Several governmental and university studies, as well as a number of independent scientists, have raised concerns and cautions on this point.*

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* See for example, James W. Gillett, et. al., Potential Impacts of Environmental Release of Biotechnology Products: Assessment, Regulation and Research Needs, Ecosystems Research Center, Cornell University, February 1985; 'Biotechnoogy Products: EPA Finds Gaps in Risk Assessment', Chemical & Engineering News, 17 February 1986, pp. 6-7; Martin Alexander, 'Ecological Consequences: Reducing the Uncertrainties', Issues in Science & Technology, Spring 1985, pp. 57-68; Robert K. Colwell, et.al., 'Genetic Engineering in Agriculture', Letter to the Editor, Science, 12 July 1985, pp. 111-112; Eugene P. Odum, 'Biotechnology and the Biosphere', Letter to the Editor, Science, 27 Sept 1985, p. 1338; 'Genetic Engineering', Letters to the Editor, from Richard E. Lenski and Bruce Levin (pp. 13-14), and Philip J. Regal (pp14-15), Issues in Science & Technology, Summer 1985; and David Pimentel, 'Genetic Engineering for Biological Control: Environmental Risks', GeneWATCH, Nov-Dec, pp. 5-6.

Second, the existing interim regulatory system for biotechnology has failed to instill confidence in the government's ability to regulate the industry, to inform and involve the broader public, and to send clear signals about what will be regulated.

Third, there is a growing sense of confusion and mistrust of both the Administration and industry activities, brought on by incidents of data fasification, improper approvals, lack of notification to local and other federal officials, inter- and intra-agency turf fighting, missed deadlines, key personell changes and philosophical shifts in the Administration's working group on biotechnology, and general lack of leadership.

In all fairness to the Administration -- which has now had the regulatory ball in its court for more than two years now -- we believe it is time for Congress to take charge of this issue with legislation, clarifying the regulatory system, while providing the public assurances that the environment and public health and safety will be protected.

While several subcommittees in Congress have held hearings on various aspects of biotechnology, and while GAO and OTA have completed several useful studies, papers, and investigations of federal agencies such as USDA, no Congressional committee has yet undertaken a systematic review of existing laws for their adequacy in regulating biotechnology. Rather, Congress has relied on the Administration to make that judegment. Yet, in our view, Congress and the general public should not be comforted by agency-drawn 'points-to-consider' or 'memoranda of understanding' as the basis for 'filling the cracks' between existing laws, or as the bridges over the gray areas where no agency appear to have a clear charge. But the real problem here is that the Administration appears to be the sole actor in this debate, more or less determining the boundaries of the debate, putting Congress in a reactive mode rather than that of a policy formulator.

THE ADMINISTRATION'S RECORD

The Environmental Policy Institute is concerned about the structure and orientation of the Administration's regulatory system, especially the way that prposed system has evolved over the last 2 years. We believe that the proposed regulatory framework is a patchwork quilt of regulatory convenience that initially grew out of the Administration's interest in keeping

EPA from assuming the lead on the deliberate release question, and simultaneously, keeping Congress from drafting new legislation. In addition, the departments of State and Commerce, as well as OMB, have also shaped the Adminstration's regulatory approach, which at times has appeared more concerned about international competitiveness than public health and safety.

Further, the creation last November of the Biotechnology Science Coordinating Committee (BSCC) is, in our view, another structure of convenience, established under the auspices of the National Science Foundation's Federal Coordinating Council for Science, Engineering and Technology for the expressed purpose of 'science coordination'. But make no mistake about BSCC's real mission here: to define what biotech products the federal agencies will and will not regulate -- with emphasis recently on the will not.

For example, we understand that the forthcoming version of the regulatory framework will propose to exempt genetically engineered organisms that have genes deleted, as well as those engineered only to contain 'non-coding regulatory sequences' -- two definitional strategies that the BSCC has drafted, and as I understand it, imposed upon certain agencies. This is not science coordination, but rather policy determination: a policy that says the Administration is willing to play Russian roulette with certain kinds of organisms released into the environment.

Several scientists have already expressed concern over these proposed Administration exemptions. For example, M.I.T. biologist Jonathan King has stated: 'It is a medieval scientific view that a deletion is automatically less risky.' The deletion of a gene, says King, 'can have a wide range of effects'.

Similarly, Cornell University biochemist Liebe Cavalieri has stated that the deletion of DNA segments does not necessarily mean that you have changed just one characteristic. In citing the 'ice-minus' bacteria which have had a single gene deleted, he notes: 'The deletion of the DNA segment responsible for the ice nucleating capability in the deletion mutants does not necessarily mean that there has been only a loss of ice nucleation character and that the behavior of the deletion mutant will be the same in all other characteristics. It is well established that the altering of a genotype, even limited to the change of a single gene, alters the metabolism of the bacteria. The gene product (i.e., the ice nucleation capability) may well have other functions in the normal physiology of the bacteria.'

Further, the Adminstration's proposal to exempt those organisms which have had 'non-coding regulatory sequences' changed is equally alarming. Apparently, scientists who have served with the NIH/RAC had grappled with this very issue several years ago, and concluded that non-regulatory sequences could be just as powerful as coding sequences (check), which makes the Administration's proposed exemption in this area even more of a puzzle, suggesting a lack of communication with NIH, sheer scientific ignorance, or intentional and knowing action for whatever purpose.

We are greatly dismayed by the Adminstration's plans to exempt such genetically-altered organisms from stringent environmental reviews, especially at this early stage of experience with biotechnology.

For these and other reasons, the Environmental Policy Institute does not believe the BSCC should be sanctioned and institutionalized by Congress, as would be the case if H.R. 4452 were enacted. In fact, we do not favor a role for the BSCC at all, but more on that later.

What the BSCC and the Administration seem intent on doing is to let any agency with an affected constituency have a hand in reviewing and regulating genetically-altered organisms destined for environmental release. Quite frankly, that is no way to insure careful environmental review. And given the bickering and turf fighting that have gone on already over the framework itself, such delay would only become further institutionalized if the Administration's plan becomes the accepted system.

I would now like to turn to the example of USDA to illustrate why I believe the Administration is on the wrong course with its regulatory framework -- and here my remarks are focused solely on the question of deliberate release.

Various analysts and reviewers* who have examined USDA's statutes and authorities for their adequacy in regulating biotechnology have generally found considerable shortcomings. Some of these are as follows:

o statues generally lack provision for agency notification requirements;

o statutes are generally not equipped to deal with 'unknowns' and 'potential risks' of genetically-altered organisms;

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* See for example, 'Biotechnology: A Legal/Regulatory Analysis', A Paper Prepared in Conjunction with the Second Annual Brookings Conference on Biotechnology, 18-19 February 1986; Skip Stiles, 'Statutory Review of FIFRA and USDA Authorities', Presented at the Second Annual Brookings Biotechnology Conference, 18 Feb 1986; and Margaret G. Mellon, 'The Agricultural Statutes As A Basis For Regulating The Release of Engineered Organisms', Testimony before The Senate Public Works Subcommittee on Toxic Substances, 16 May 1986.

o statutes do not apply to organisms other than those that are known pathogens of plants or livestock (e.g., beneficial organisms and non-infectious agents of animal diseases can be altered with biotechnoogy, but are not covered by the USDA statutes*);

o statutes such as the Virus Serum Toxin Act (VST) only apply to the interstate or intrastate 'movement' or shipment of certain agents;

o statutes such as the the Plant Pest and Noxious Weed Acts, and the 1903 Act, as presently structured, have no beforehand testing requirements to determine if new organisms might be pests, noxious weeds, or contagious agents;

o statutes such as the Plant Pest and Noxious Weed acts have no provisions for routine data submissions;

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* In one interesting USDA statement on this point, APHIS Administrator Bert Hawkins, testifying before the House Agriculture Subcommittee on Oversight in July 1983, said: 'At this time, APHIS can regulate only those organisms that can be defined as pests; the Environmental Protection Agency (EPA) can regulate organisms that are defined as pesticides and can, under the authority of FIFRA, exempt certain organisms from regulation if it is determined that ehy are adequately regulated by another agency. Several such organisms have been exempted, yet APHIS cannot, under our present authority, regulate those organisms not determined to be pests. Numerous organisms remain unregulated and can move freely within the U.S.(emphasis added). The scientific community has been very cooperative in voluntarily keeping us appraised of their activities. As this field expands into broader commercial development, however, we have no assurance that such cooperation will continue and no authority to prevent or restrict movement of questionable organisms. New developments in the field of genetically engineered organisms will further challenge our authority to act. As we explore new organisms for their potential beneficial effects on plant pests, we must be careful that they are not pests themselves.'

o statutes such as the Plant Pest and Noxious

Weed Acts have no provisions for appealing an agency decision, either for citizens or manufacturers;

- the VST does not cover research activities;

- the VST's pre-market testing and review of animal biologics are applicable to adverse health impacts on treated livestock, not the broader environmental and ecological effects of released organisms.

In sum, the USDA statutes, with the possible exception of the VST, are after-the-fact registrars of what has already happened --essentially lists of pests, contagions, and infectious agents that have already expressed themselves on the landscape -- offering remedies for a future that deals with those agents, and not new mutants, genetic exchanges, or the creation of potentially vulnerable situations that may result from the use of gentically-altered organisms. Rather than being anticipatory environmental statutes designed to prevent problems, the USDA statutes are after-the-fact enumerators and catalogs. Moreover, the USDA statutes are generally protective of agriculture, not the larger environment or the subtleties of ecological systems.

In addition to the shortcomings of the USDA statutes themselves, there is a larger problem having to do with USDA's historical record and the department's general approach to environmental protection.

USDA: THE PESTICIDE EXPERIENCE

In 1947, USDA was given the primary authority to regulate pesticides with the passage of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

In 1962, Rachel Carson's Silent Spring was published, and USDA faced a good deal of criticism about the way it was handling pesticides.

By 1964, USDA agreed to permit HEW and the Department of the Interior to help determine if pesticides under review constituted a threat to human health or to fish or wildlife. But according to Lewis Regenstein, author of America the Poisoned, 'USDA never took these provisions seriously nor attempted to enforce them'.

In 1968, GAO issued a report documenting USDA's failure to enforce FIFRA, citing numerous examples where the agency allowed pesticides to be used over the objections of the U.S. Public Health Service and other agencies. GAO also noted that despite numerous illegal actions by some shippers, no USDA prosecutions under FIFRA had occurred in 13 years.

In November 1969,the House Government Operations Committee issued a scathing report that detailed how USDA ignored its responsibilities for regulating pesticides under FIFRA. That report described how the registration of pesticides was granted almost automatically, and that more than 45,000 pesticides were registered as 'safe and effective' without any meaningful review. The report also revealed that HEW had objected to proposed registrations for more than 1,600 pesticides between 1964 and 1969, and that USDA had approved pesticide products which it knew or should have known were practically certain to result in the illegal adulteration of food.

By December 1970, EPA was created, and the jurisdiction for pesticides was shifted there from USDA, but not without considerable USDA baggage.

As a society, we are still paying for USDA's early jurisdiction in pesticides, as the long and bitter re-registration process and FIFRA reauthorization battle now attest. We should not make the same mistakes with biotechnology.

Further, if one examines recent USDA history, it is clear that the agency's interest in protecting the environment has been very short-lived, where it has existed at all.

In 1978, for example, USDA opened an Office of Environmental Quality to coordinate environmental issues within USDA and represent the Office of the Secretary on broad departmental issues. At that time, there was even an Assistant Secretary for Natural Resources and Environment, and even a few people working on organic agriculture. But by 1981, all of that was dismantled or 'reorganized', the remnants of which were sent off to the Siberian extremeties of the agency to die a slow death.

All of this is to say that in our view USDA is not an agency with an environmental mission. Rather, its mission is to maximize agricultural production, a goal that is often at odds with environmental protection. In fact, that primary mission of USDA was on view in the recent handling of the genetically engineered pseudorabies vaccine; a vaccine wich USDA, licensed without first considering its environmental impact, notifying other agencies, or going through already operative channels to review the vaccine's special status as a recombinant organism.

Yet USDA is not the only agency without a clear mission to protect the environment. I would also place State, Commerce and the BSCC in that category as well. Which brings me to my next point.

A BIOTECHNOLOGY SCIENCE BOARD AT EPA

As the Congress and the federal agencies move toward the resolution of some final regulatory mechanism for biotechnology, those products destined for environmental use deserve special attention. And here, I am not just talking about agriculture either. Every environmental media -- air and soil, fields and forests, oceans and estuaries-- will be affected by the thousands of genetically-altered organisms to come in the years ahead. Whether it's genetically-engineered organisms for enhanced oil recovery, toxic waste clean up, hard rock mining, forestry use, or the release of superfish in the Great Lakes, ecologies of all kinds will be affected.

It stands to reason then --especially when considering potential environmental effects of organisms that will be released into the air, soil, or water -- that environmental science and environmental protection be the paramount considerations in any regulatory scheme.

For these reasons, we believe that EPA should be at the center of the 'deliberate release' regulatory system, not the BSCC or any other White House entity. In our view, EPA is the only federal agency that has a clear mission for environmental review and protection. None of the other federal agencies have this mission as their primary goal. Therefore, EPA needs to be the first reviewer of all applications for genetically altered organisms destined for use in the environment.

And here we are not necessarily proposing something new, but rather a variation one proposal offered by the Administration in December 1984, called the Biotechnology Science Board. The proposed Board I am offering here however, would operate under EPA auspices, on a level with the Administrator's office, and would, in effect, be the 'traffic cop' for all biotechnology applications that involve a deliberate release. This BSB would be comprised of the EPA Administrator and 4 other members and a scientific staff. The purpose of this Board would be to review all deliberate release applications to determine the needed course of review and what appropriate expertise in other federal agencies should be utilized, depending on the proposed use, environmental medium involved and geographic location of the release. This new BSB would also set deadlines, hold public hearings on novel applications, and make a final determination on a proposed field test or commerical release. An appeal process, open to citizens, researchers and manufacturers, would be available to challenge commission decisions.

One of the possible functions of the BSB, as we envision that board, would be to raise questions of alternative actions or products for all proposed genetically-altered organims destined for environmental release. In fact, at the outset of the permit process, whether for a field test or larger commercial release, the BSB could require all applicants to make a statement regarding alternative methods, products or practices currently available or known to be in research that could accomplish the same results.*

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* For example, one of the arguments for the recent approval of pseudorabies vacine by the Biologics Corp. was the rise in the incidence of pseudorabies in the last 10 years (which ironically coordinates alomost exactly with the invention of the conventional vaccine), recently estimated to affect some 10% of the nation's hog herd. Yet, might there be other factors which have also contributed to the ise of this disease, such as the onset of larger confinement operations in the hog industry where as many a 1 million hogs are reared together in close quarters in one building. Similarly, a decline in state and/or federal funding for herd monitoring and transport of positive pseudorabies carriers moving ffrom one state to the next? In this instance, the alternative of tough state monitoring and enforcement might be one strategy that alleviates the pressure for rushing to market with a new genetically altered drug.

H.R. 4452, The Biotechnology Science Coordination Act of 1986

The Environmental Policy Institute wishes to commend the Chairman of the full committee, the members and staff of these subcommittees, and other committee members and staff who have taken the initiative to put together H.R. 4452, one of the first pieces of legislation that attempts to address some of the science and regulatory problems concerning biotechnology. While this bill includes some very laudable features, including the use of a permit approach and some valuable public notification provisions, we would suggest that the subcommittees may want to consider extensive revisions to this legislation, or starting with a new bill, given the Adminstration's revisions to their framework and the testimony that has been presented today and at other congressional hearings. We are not prepared to support H.R. 4452 at this time, although we do agree that legislation is certainly needed to clarify the situation and to assure the public that safeguards and protections will be in place.

The Importance of Public Participation

As the recent protests of local public officials and citizens in Monterey County, California and St. Charles County, Missouri make plain, and as more field tests and larger commerical releases come to fore, there will be an increasing need to involve a borader segment of the public in biotechnology regulation that has thus far been involved. EPI therefore urges the members of this committee to incoporate strong citizen participation provisions in its legislation, ranging from public notice and information access to rights of appeal and even citizen suits. For without involving and nforming the public on a continuing basis, each and every field test of a novel organism is likely to meet with resistance.

Speaking at a National Academy of Sciences' biotechnology forum last year, former EPA Administrator William B. Ruckelshaus told his listeners that public participation with biotechnology had to go beyond the Federal Register.

'If the government doesn't do its job', he said, 'it is unlikely that the United States will stay ahead either in the research or the commercialization of this new technology'. And he added that there were two ways in which the government might not do its job right. 'One is that the government would do too much; there would be very heavy handed regulation, needless time-delaying, red tape, nitpicking, an unwillingness on the part of government ever to make a decision. If there is too much regulation, we could stifle this emerging technology. On the other side, that could happen also if there is too little regulation, or if it is unwise or sloppy or not open. (That) could just as certainly doom our efforts to take advantage of our current lead'.

ENVIRONMENTAL POLICY INSTITUTE

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NEWS RELEASE

Contact: David K. Martin
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WASHINGTON, D.C. -- A leading critic of biotechnology told a Congressional subcommittee today that the "Environmental Protection Agency (EPA) is the only federal agency that has a clear mission for environmental protection" and ought to house a Biotechnology Science Board to review all genetically-engineered organisms destined for commercial uses in the environment.

Jack Doyle, director of the Agricultural Resources Project at the Environmental Policy Institute (EPI), made the statement in remarks prepared for delivery to a joint hearing of two House science subcommittees regarding H.R. 4452, the proposed Biotechnology Science Corrdination Act of 1986. EPI is a Washington-based nonprofit public interest organization involved in a variety of environmental issues.

Doyle, who also is author of the widely acclaimed book, "Altered Harvest: Agriculture, Genetics and the Fate of the World's Food Supply," accused the Reagan Administration of being "willing to play Russian roulette" by exempting certain kinds of genetically-engineered organisms from regulation with new guidelines.

He also charged that the Administration was trying "to keep EPA from assuming the lead on the deliberate release question," while pre-empting Congress from writing new legislation.

"EPA should be at the center of the 'deliberate release' regulatory system," Doyle told the subcommittees, "not any White House entity. In our view, EPA is the only federal agency that has a clear mission for environmental review and protection

(more)

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Doyle went on to outline a proposal for a "Biotechnology Science Board" within EPA, which would operate "on a level with the administrator's office" and serve as a "traffic cop" for the federal review of all biotechnology applications that involve the environmental release of genetically-altered organisms.

Doyle also questioned the wisdom and legal basis of the U.S. Department of Agriculture's (USDA) involvement in regulating genetically-engineered organisms, citing that agency's historic failure in regulating pesticides.

"In our view USDA is not an agency with an environmental mission. Rather, its mission is to maximize agricultural production, a goal that is often at odds with environmental protection," he said.

Doyle said there is an urgent and compelling need for the federal government to take the lead in providing safeguards, protections and orderly procedures regarding the introduction of genetically-altered organisms into the environment. However, he added, H.R. 4452 might not be the right answer to the problem, although he praised the subcommittees for producing the measure as a beginning.

Doyle concluded by suggesting that the subcommittees consider "extensive revisions" to their legislation, or "start with a new bill. In any case, he said, "legislation is certainly needed to clarify the situation and to assure the public that safeguards and protections will be in place."

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(EDITORS NOTE: Jack Doyle is with EPI, a private organization, not to be confused with EPA.)

Mr. VALENTINE [presiding]. Thank you, Mr. Doyle. Dr. Glass.

Dr. GLASS. Thank you, Mr. Chairman. BioTechnica International welcomes the opportunity to testify today and to comment from the perspective of a small company on the proposed legislation, H.R. 4452, and its potential impact on the development of the agricultural sector of the biotechnology industry.

BioTechnica is a 5-year-old genetic engineering firm located in Cambridge, MA, now employing about 100 people. The company is developing products in the areas of agriculture and dental diagnostics. Our interests in agriculture include improved microbial inoculants for silagemaking and plant growth promotion, and the development of herbicide tolerant varieties of important crop plants. We are also developing microbial production systems and other genetic engineering technologies for the agriculture, health care and food and beverage industries.

I would like to begin with some general comments on the regulation of agricultural biotechnology, after which I will comment more specifically on those provisions of H.R. 4452 affecting agricultural biotechnology. My answers to the several specific questions about the bill which you have posed can be found in my written statement.

BioTechnica believes that new legislation is not needed for the adequate regulation of biotechnology. The products being developed using the newly-invented techniques of genetic engineering are similar to products manufactured by conventional processes. This is particularly true in agriculture, where the new genetic engineering technologies can be seen as a logical extension of the more traditional kinds of genetic engineering which have been used to improve agricultural productivity for centuries.

The use of these new techniques of genetic engineering allows valuable improvements in agriculturally useful organisms to be made more quickly and with a greater degree of predictability than would be possible using traditional genetic engineering. Yet the end products themselves will not be appreciably different than those produced by the classical methods.

The vast majority of the products that will arise from biotechnology will fall into existing categories, and will thus be covered by existing laws and regulations. Biotechnology products should be regulated on a product-by-product basis, by the Federal agency having experience with such products, without the need for new legislation, and indeed we just heard Commissioner Young of the FDA mention the numerous products that FDA has approved using their existing statutory authorities.

BioTechnica agrees that regulation of biotechnology products is desirable to assure the public that their health and safety are adequately protected and that the environment is not endangered. We are concerned, however, that the earliest stages of product development and testing not be subjected to unnecessarily strict regulation, which could cause significant delays in product introduction, at a cost which could have serious consequences for small companies. Instead, we favor a realistic and predictable regulatory regime, which would allow companies to know in advance the requirements for safety testing, so that they could incorporate into their strategic planning the time and cost needed to meet these requirements.

We had previously put forward some recommendations for the basis of such a general regulatory regime in an article coauthored by Dr. Ralph Hardy and myself, which is referenced in my written statement. To summarize some of the major points in this article, we believe that there are no special risks inherent in the new genetic engineering technologies that would compel additional regulatory requirements. These techniques should be seen as alternative manufacturing methods, and risk analysis should therefore focus on the end products rather than on the process.

Regulatory decisions should be based on proper scientific review by qualified scientists and the scientific review should draw upon the considerable experience that exists from the use of the products of traditional genetic engineering in manufacturing and in agriculture. Regulation of agricultural biotechnology must be considered in light of its potential effect on the development of this important sector of the biotechnology industry.

The potential economic impact and societal benefits of biotechnology in agriculture are well known, and the products of this technology could revolutionize agriculture possibly becoming a stimulus for the revitalization of America's competitive position in agriculture. In light of this, the United States must insure that the regulatory regime ultimately put into place for these products is not overly severe so as to stifle the field's development. Although regulation of agricultural biotechnology is necessary and should include appropriate risk assessments, regulation must be consistent with the potential risks of the product, and not impose unnecessary requirements.

This is particularly important in light of the way in which agricultural products have historically been developed. New crop varieties, pesticides and other agrichemicals are generally developed through an iterative process of field testing, where a large number of potential product candidates are evaluated in the field over the course of several planting seasons, to select those entities which meet the desired performance characteristics. Such an approach is necessary because greenhouse experiments cannot adequately predict a product's performance under the more demanding conditions of the open field. Therefore, companies must generally conduct field tests at a very early stage of product development, and these initial field tests will involve highly preliminary product candidates.

Placing a large regulatory burden on these limited-acreage preliminary tests would lead to excessive time and cost requirements for safety testing at a very early stage of product development. If this occurs, companies, particularly small ones, must seriously consider whether to continue development of agricultural biotechnology products.

We do agree that the Government and the public have a right to know that field tests, once they are approved by Federal agencies, are being conducted safely and with the appropriate monitoring, but because of the current uncertainty here in Washington over the risk assessment methods, we have reached a logjam where companies are unable to receive approvals to carry out field tests of genetically engineered micro-organisms.

As a possible solution to this problem, my colleague Dr. Hardy has suggested that the Government establish publicly owned, professionally managed field testing sites, at which companies could use their own employees to conduct field tests under the oversight and supervision of Government personnel and biosafety committees. In this way, companies would not be blocked from conducting these preliminary field tests, and the public can be assured that the tests would be properly conducted.

Before turning to the specific provisions of H.R. 4452, I would like to comment on the Federal Government's approach to regulation of agricultural biotechnology products in two specific areas. Although the long-awaited revised agency policy statements have not yet been made public, we have two specific concerns about this regulation based on recent events.

First, is the issue of jurisdiction over agricultural micro-organisms. Both the EPA and the USDA have expressed their intention to regulate genetically altered microorganisms used in agriculture, and this would include microbial soil inoculants such as the nitrogen-fixing bacteria, rhizobia, which are being developed by BioTechnica and other companies.

We understand that the Cabinet Council Working Group has discussed this potential jurisdictional overlap, at length in the past several months, but to our knowledge, the situation has not yet been resolved. It is imperative that there be no dual regulatory jurisdiction over agricultural micro-organism products. One of these agencies must be selected as the lead agency with principal or sole responsibility for approving field tests and products.

Second, we are concerned that the USDA clarify its own review procedures for those products for which it has jurisdiction. An intramural dispute between USDA's research agencies and its regulatory agency, APHIS, has lately been publicized. These agencies must together agree on a unified approach to the regulation of biotechnology, including proper scientific review of field test proposals and product licensing applications, utilizing qualified scientific experts whether, inside or outside the department. For this reason, we support the establishment of a Recombinant DNA Advisory Committee within USDA, and we urge that it be used as a resource by USDA's regulatory branch to ensure the public of the adequacy of its review process. This dispute must not endanger public confidence in USDA's ability to use its considerable expertise to adequately regulate biotechnology.

I would now like to offer some specific comments on H.R. 4452 and its provisions regarding USDA on agricultural biotechnology. BioTechnica does not favor passage of the bill. The bill would impose an intricate permitting scheme that would cover a great number of uses of genetically engineered organisms in manufacturing or in the environment. We object to this scheme for the following reasons.

First, the bill would enact a detailed permitting scheme that, because of its statutory nature, would be highly inflexible, and could not easily be amended at some future time, should new scientific knowledge warrant reduced requirements. If a strict regulatory regime is to be instituted at this time, it should not be enacted through legislation, which would be difficult to change, but through agency regulations or guidelines, which can more easily be amended, with ample opportunity for public comment.

Second, the bill would require substantial data collection and a lengthy regulatory review to obtain a permit for initial use of organisms in the environment. Such requirements are too stringent, given the preliminary nature of these tests, as I discussed earlier.

Next we object to the bill's scope as being too broad in two regards. First, we do not believe that contained manufacturing activities should be subject to stringent permitting requirements. When conducted according to good manufacturing practices and/or the NIH large-scale guidelines, fermentations pose little risk to workers and only a minimal chance of a significant accidental release.

Second, the bill's use of the phrase, "manufacturing on an experimental basis" is to broad, and could be interpreted to cover any basic research experiment in which engineered organisms are grown. Requiring permits for such research would have a chilling effect on the conduct of research in molecular biology at universities or other locations.

Finally, industry does not, in general, favor a permitting scheme where the burden of proof is on the applicant, in particular one with such an open-ended requirement for proof of safety. Absolute safety can never be proven, and levels of risk must be weighed in risk-benefit analyses on a product-by-product basis.

Regulatory reviews must have defined end points, where the amount and type of data to be submitted are reasonable and are known in advance by the applicants.

Mr. Chairman, at this time, I would like to conclude my oral testimony and mention again that my responses to the specific questions on the bill are included in my written statement, and I would be glad to answer questions on either those or anything else.

[The prepared statement of Dr. Glass follows:]

STATEMENT OF DAVID J. GLASS, PH.D., DIRECTOR, PATENTS AND REGULATORY AFFAIRS, BIOTECHNICA INTERNATIONAL, INC.

Thank you, Mr. Chairman. My name is David Glass, nad I am director, patents and regulatory affairs at BioTechnica International, Inc. BioTechnica is a 5-year-old genetic engineering firm located in Cambridge, Massachusetts, now employing about 100 people. The company is developing products in the areas of agriculture and dental diagnostics; our interests in agriculture include improved microbial inoculants for silage-making and plant growth promotion, and the development of herbicide tolerant varieties of important crop plants. We are also developing microbial production systems and other genetic engineering technologies, for the agriculture, health care and food and beverage industries. We welcome the opportunity to testify today, and to comment from the perspective of a small company on the proposed legislation, H.R. 4452, and its potential impact on the development of the agricultural sector of the biotechnology industry.

I would like to begin with some general comments on the regulation of agricultural biotechnology, after which I will comment more specifically on those provisions of H.R. 4452 affecting agricultural biotechnology. I will also answer the several specific questions about the bill which you have posed.

BioTechnica International, like many other companies in our field, believes that new legislation is not needed for the adequate regulation of biotechnology. The products being developed using the newly invented techniques of genetic engineering are similar to products manufactured by conventional processes. This is particularly true in agriculture, where the new genetic engineering technologies can be seen as a logical extension of the more traditional kinds of genetic engineering which have been used to improve agricultural productivity for centuries. Plant and animal breeding and the selection of improved microorganisms by classical mutation are a kind of genetic engineering where changes are made at the level of the whole organism. The newer technologies allow more precise changes to be made either at the level of the cell (e.g., techniques such as plant tissue culture or somaclonal variation) or at the level of the actual molecules carrying the genetic code (e.g., recombinant DNA technology). The use of "cellular" and "molecular" genetic engineering allows valuable improvements in agriculturally useful organisms to be made more quickly and with a greater degree of predictability than would be possible using "whole organism" genetic engineering, yet the end products themselves will not be appreciably different than those produced by the classical methods.

The vast majority of the products that will arise from biotechnology will fall into existing categories, and will thus be covered by existing laws and regulations. In the area of health care, for example, over 100 in vitro diagnostic products and several human and animal therapeutic agents produced by cellular and molecular genetic engineering have been approved for manufacture and sale under existing regulations. Biotechnology products should be regulated on a product-by-product basis, by the federal agency having experience with such products, without the need for new legislation. The few categories of product for which existing regulations appear not to apply could be covered by the extension of existing regulatory authority by the appropriate agency.

BioTechnica agrees that regulation of biotechnology products is desirable, to assure the public that their health and safety are adequately protected and that the environment is not endangered. We are concerned, however, that the earliest stages of product development and testing not be subjected to unnecessarily strict regulation, which could cause significant delays in product introduction, at a cost which could have serious consequences for small companies. Instead, we favor a realistic and predictable regulatory regime, which would allow companies to know in advance the requirements for safety testing, so that they could incorporate into their strategic planning the time and cost needed to meet these requirements. This would be of particular importance for agricultural products requiring evaluation in the field, where current confusion over regulatory requirements has been a major factor delaying proposed field tests.

BioTechnica has previously put forward some recommendations for the basis of a general regulatory regime for biotechnology, in an article coauthored by Dr. Ralph W.F. Hardy, BioTechnica's Deputy Chairman, and myself, in the Spring 1985 Issues in Science and Technology (Volume I, number 3, pages 69-82). Copies of this article have been provided for inclusion into the record. To summarize some of the major points, we believe that there are no special risks inherent in the new genetic engineering technologies that would compel additional regulatory requirements. These techniques should be seen as alternative manufacturing methods, and risk analysis should therefore focus on the end products rather than on the process. Regulatory decisions should be based on proper scientiific review by qualified scientists, and the scientific review should draw upon the considerable experience that exists from the use of traditional genetic engineering in manufacturing and in agriculture.

Regulation of agricultural biotechnology must be considered in light of its potential effect on the development of this important sector of the biotechnology industry: According to a recent report by the Office of Technology Assessment, over 50 companies in the United States are pursuing applications of biotechnology in crop agriculture, with about half these firms being small startup companies. Biotechnology promises to have an enormous economic impact in the years to come, possibly affecting much of the $450 billion worldwide farm supply market.

Potential products in this area include novel microbial pesticides that could reduce the use of toxic chemicals in agriculture, soil inoculants with improved abilities to fix nitrogen or otherwise increase crop productivity (again, reducing the need for agrichemicals), and a wide range of improvements to crops themselves, to impart resistence to diseases, environmental stress or toxic herbicides, or to improve nutritional qualities. Together, these products could revolutionize agriculture, and be a stimulus for the revitalization of the competitive position of American agriculture.

In light of this great potential for agricultural biotechnology, the United States must ensure that the regulatory regime ultimately put into place for these products is not overly severe so as to stifle the field's development. Although regulation of agricultural biotechnology is necessary, and should include appropriate risk assessments, regulation must be consistent with the potential risks of the product, and not impose unnecessary requirements.

This is particularly important in light of the way in which agricultural products have historically been developed. New crop varieties, pesticides and other agrichemicals are generally developed through an iterative process of field testing, where a large number of potential product candidates are evaluated in the field over the course of several planting seasons, to select those entities which meet the desired performance characteristics. Such an approach to product evaluation is necessary because greenhouse experiments cannot adequately predict a product's performance under the more demanding conditions of the open field. Therefore, companies must generally conduct field tests at a very early stage of product development, and these initial field tests will involve highly preliminary product candidates, whether the product is produced by traditional means or by one of the new biotechnologies. Placing a large regulatory burden on these limited-acreage preliminary field tests would lead to excessive time and cost requirements for safety testing at a very early stage of product development. If this occurs, companies (particularly small ones) must seriously consider whether to continue development of agricultural biotechnology products.

In addition, this iterative field testing regime is highly dependent upon the planting seasons. A seemingly minor delay in field test approval of a few weeks or months can lead to the loss of an entire year, if the delay causes a planting season to be missed. For this reason, regulatory reviews must be timely, preferably with a reasonable deadline for agency action.

The government and the public have the right to know that field tests approved by federal agencies are conducted safely and with the appropriate monitoring. However, because of the current uncertainty over risk assessment methods, we have reached a logjam where companies are unable to carry out field tests of genetically engineered microorganisms. As a possible solution to the problem, my colleague Dr. Hardy has suggested that the government establish publicly-owned, professionally-managed field testing sites, at which companies could use their own employees to conduct field tests under the oversight and supervision of government personnel and biosafety committees. In this way, companies would not be blocked from conducting these preliminary field tests, and the public can be assured that the tests would be properly conducted.

Before turning to the specific provisions of H.R. 4452, I would like to comment on the federal government's approach to regulation of agricultural biotechnology products in the specified areas. Although the long-awaited revised agency policy statements have not yet been made public, we have two specific concerns about this regulation based on recent events.

First is the issue of jurisdiction over agricultural microorganisms. In their December 1984 policy statements, both the Environmental Protection Agency and U.S. Department of Agriculture have expressed their intention to regulate genetically altered microorganisms used in agriculture, and this would include microbial soil inoculants such as the nitrogen-fixing bacteria Rhizobia, which are being developed by BioTechnica and other companies. In the months since these notices, we understand that the Cabinet Council Working Group has discussed this potential jurisdictional overlap at length in the past several months, but to our knowledge, the situation has not yet been resolved. It is imperative that there be no dual regulatory jurisdiction over agricultural microorganism products. One of these agencies must be selected as the lead agency, with principal (or sole) responsibility for approving field tests and products. BioTechnica is hoping to conduct a field test of our Rhizobium strains next year, which would require us to prepare a regulatory submission in the next several months. We and other companies must know which agency will be regulating our products, so that we can begin the process with the appropriate agency.

Secondly, we are concerned that USDA clarify its own review procedurs for those products for which it has jurisdiction. An intramural dispute between USDA's research agencies and its regulatory agency APHIS has lately been publicized. These agencies must together agree on a unified approach to the regulation of biotechnology, including proper scientific review of field test proposals and product licensing applications, utilizing qualified scientific experts whether inside or outside the Department. For this reason, we support the establishment of a Recombinant DNA Advisory Committee within USDA, as proposed by H.R. 4452, and we urge that it be used as a resource by USDA's regulatory branch to ensure the public of the adequacy of its review process. This dispute must not endanger public confidence in USDA's ability to use its considerable expertise to adequately regulate biotechnology.

I would now like to offer some specific comments on H.R. 4452 and its provisions regarding USDA (Title on agricultural bio. IV). BioTechnica does not factor passage of this bill. The bill would impose an intricate permitting scheme that would cover a great number of uses of genetically engineered organisms in manufacturing or in the environment. We object to this scheme for the following reasons.

First, in the bill would enact by statute a detailed permitting scheme that, because of its statutory nature, would be highly inflexible, and could not easily be amended at some future time, should new scientific knowledge warrant reduced requirements. One of the strong points of the NIH recombinant DNA Guidelines has been their ability to be amended as the field evolved. If a strict regulatory regime is to be instituted at this time, it should not be enacted through legislation, which would be difficult to change, but through agency regulations or guidelines, which can more easily be amended, with ample opportunity for public comment.

Second, the bill would require substantial data collection and a lengthy regulatory review to obtain a permit for "initial use" of organisms in the environment. Such requirements are too stringent, given the preliminary nature of these tests. As I discussed earlier, regulations such as these will stifle the development of agricultural biotechnology, and will delay product introductions.

Scope of coverage. Next we object to the bill's scope as being to broad in two regards. Firstly, we do not belive that "contained manufacturing" activities should be subject to stringent permitting requirements. When conducted according to good manufacturing practices and/or the NIH Large Scale Guildelines, fermentations pose little risk to workers and only a minimal chance of a significant "accidental release". Fermentations of organisms modified by cellular or molecular genetic engineering pose no greater risk than fermentations of the "whole organism" engineered (i.e., mutated) organisms now widely used in manufacturing. Secondly, the bill's use of the phrase "manufacturing on an experimental basis" is too broad, and could be interpreted to cover any basic research experiment in which engineered organisms are grown. Requiring permits for such research would have a chilling effect on the conduct of university resarch in molecular biology at universities or other locations.

Burden of Proof. Finally Industry does not, in general, favor a permitting scheme where the burden of proof is on the applicant, in particular one with such an open-ended requirement for proof of safety. Absolute safety can never be proven, and levels of risk must be weighed in risk-benefit analyses on a product-by-product basis. A requirement that a company prove that there is no "unreasonable risk" associated with its proposed use could lead to a drawn-out regulatory review process whereby an agency could continually request more and more data. Regulatory reviews must have defined end points, where the amount and type of data to be submitted are reasonable and are known in advance by the applicants.

Finally, we have the following responses to the six specific questions which you have posed, which should be considered in light of our previously-stated position on the bill itself.

1. Does the Biotechnology Science Coordinating Committee provide the proper oversight and coordination? We have no objections to the establishment of the BSCC to coordinate and standardize scientific review procedures in the regulatory process, provided that the BSCC has no independent regulatory powers nor the authority to review licensing decisions made by the agencies. However, we believe that it is more appropriate for the BSCC to be chartered under the Federal Coordinating Council for Science, Engineering and Technology [FCCSET], than under the proposed Title I of H.R. 4452. It would be far easier to change the BSCC's mission or to disband it altogether (if future circumstances so warranted) under FCCSET than if it were legislatively empaneled under H.R. 4452.

2. Is the proposed Biotechnology Science Research Program [BSRP] an appropriate approach? BioTechnica strongly agrees that there is a need for basic research to support risk assessments in the regulatory process. However, we are unfamiliar with the Health Effects Institute, upon which the BSRP is modeled, and so cannot comment on its success or suitability for biotechnology. We have two specific comments on the BSRP. First, although private funding should be sought, we believe that the funding of basic research is primarily a function of government, so the government should bear more than 50% of the cost of such a program. Despite the importance of basic research, small companies cannot afford to bear significant costs for its support. Secondly, if such a program were to be enacted, it might better be administered by an entity inside or outside government with more experience in awarding research grants (e.g., NSF, NIH or NAS). OSTP is not a suitable location for such a program.

3. Is the definition of a genetically-engineered organism sufficient? The definition of "genetically-engineered organism" in H.R. 4452 includes only those organisms "deliberately altered to contain genetic material derived from more than one taxonomic genus". We believe a definition of such scope is acceptable, in that this would

exempt organisms created by classical mutation or breeding ("whose organism engineering") and thus not impose new regulations on previously unregulated areas. This definition would specifically exempt organisms where genetic material has been deleted, and we believe this is appropriate beacause such organisms in general present extremely low risks and are often similar to naturally occurring mutations. It might also be desirable to exempt organisms whose genetic material is derived from species or genera which exchange DNA in nature.

We are concerned about the inclusion of such a detailed definition into legislation, where it would be difficult to amend. We generally favor giving an agency the authority to define its own exemptions through regulations or guidelines, which might be more easily modified at some future time.

4. Should organisms derived through recombinant DNA techniques be subjected to federal permitting authority only when such organisms are released into the environment? As I mentioned earlier, we believe that the permitting scheme of H.R. 4452 should not cover the use of genetically altered organisms in contained manufacturing, and, if it is to be adopted at all, should cover only environmental uses of such organisms, with reduced requirements for initial, limited-acreage tests.

5. Should federal agencies continue to review all organisms intended for environmental release on a case-by-case basis just as NIH-RAC has done in the past? In the early stages of the technology, the case-by-case approach is the only feasible means of regulation. Over time, as the agencies gain experience with biotechnology products, generic categories will no doubt emerge, perhaps leading to exempted classes and/or reduced regulatory requirements for certain products.

6. What changes could be made in H.R. 4452 to remedy any regulatory deficiencies you see within the agencies? Our previous comments, particularly regarding USDA, address this question.

Mr. Chairman, this concludes my testimony. I would be glad to answer any questions that the subcommittee members may have.

Mr. **VALENTINE**. Thank you very much, Doctor. Dr. Glass, would your firm be exempt from TSCA premanufacturing notice requirements under the small business exemption, which is, as I understand it, the definition that they use of "small business" is one with less than $40 million annual sales, which I guess the definition of what is "small" and what is "large" is the subject of debate, and less than 100,000 pounds produced of the substance which is covered.

I don't want to ask you to disclose anything that is not a matter of public record.

Dr. **GLASS**. We are a public company, so certain things are public record, of course.

First of all, let me just say that I am not that familiar with the provision of the bill—of TSCA that you just mentioned, so my response is based on your description of that exemption. Unfortunately, we do not have $40 million of whatever the number was in sales, and certainly not for our initial field test would we go over the pound requirement that you have mentioned.

It is conceivable, depending on the product, at a certain point in commercial use we might exceed that, but that is just off the top of my head.

Mr. **VALENTINE**. Mr. Volkmer.

Mr. **VOLKMER**. Dr. Glass, let's say that you had genetically engineered a plant in your laboratories and you decided that you were going to go out and do a field test. Right now under present regulation law, would you be required to submit that to the USDA for review before you do a field test?

Dr. **GLASS**. And this, of course, follows up with the discussions you had with the previous panel from the USDA.

Mr. **VOLKMER**. That's right.

Dr. **Glass**. It is my understanding that under the Plant Pest Act USDA could, if it wished, promulgate regulations that could conceivably cover—well, it would authorize them to give prior review of a plant field test.

Mr. **Volkmer**. Right now you are not required.

Dr. **Glass**. I am not aware of any regulations that would currently cover that. Let me just say, though, that we would not take the step of conducting a field test without seeking some form of Government approval, and if we were in that position, we would probably approach the USDA certainly to consult them and hopefully to get some form of approval to conduct a test like that, and it is our hope, as was mentioned earlier, that USDA does promulgate regulations that would allow them to review such field tests under the Plant Pest Act.

Mr. **Volkmer**. I see right now that there is still some confusion in this whole area, is it not?

Dr. **Glass**. There seems to be. I can't answer for the Federal Government, but from a company looking at the Federal Government, it certainly seems to be.

Mr. **Volkmer**. Yes. Then the question is is the regulation going to require every plant that is genetically engineered in some way to come before USDA before it can be planted in a field test.

Dr. **Glass**. Well, let me comment on that from a scientific perspective, first. As I did say in my testimony, we expect that plants being developed by the new biotechnologies, by recombinant DNA and other techniques, really will not be a great deal different from the large number of new varieties that are introduced into this country every year and that are being field tested and being introduced with virtually no oversight.

As I said, it is not to say that there should be no regulation, and it would certainly be better for all concerned if there were to be a regulation covering field tests of plants such that the public and the Government would be assured that nothing would slip through the cracks. But I do want to assure you that limited scale field tests of plants pose far fewer problems than limited scaled field tests of micro-organisms. They are much easier contained. You can see them, et cetera.

Mr. **Volkmer**. I won't disagree with that, so let's step over to micro-organisms just for a minute, and let's say that you have genetically engineered a micro-organism to be used in the cleanup of hazardous wastes, and let's say it could come within the Toxic Substances Control Act, the TSCA, under EPA. Now, we have got a little different picture there right now also, do we not? Have you looked at TSCA?

Dr. **Glass**. Not lately, but several years ago I did.

Mr. **Volkmer**. Well, it has not changed that much, and as I understand it, you could do a field test without any prior approval by EPA.

Dr. **Glass**. Under the current R&D exemption? Is that what you are referring to?

Mr. **Volkmer**. Yes.

Dr. **Glass**. I believe so.

Mr. **Volkmer**. That's correct. If it is on land, you have got a 10-acre, and on water you have got a certain amount of surface.

Dr. GLASS. I think that is the Pesticide Act. But I think you are correct. Under the R&D exemption of TSCA, currently you would not need to file a premanufactured notice depending on how EPA chooses to define the R&D exemption.

Mr. DOYLE. If I may comment——

Mr. VOLKMER. Yes, Mr. Doyle.

Mr. DOYLE. Basically, the differences between TSCA and FIFRA is that TSCA is a notification act and FIFRA is a lot different in terms of the data submissions and the burden of proof. It is an application process.

Mr. VOLKMER. Well, the total reverse also. After you have done your field test, then you can submit it all—if it shows everything positive, you submit it to EPA, and then it is incumbent upon EPA to say that it is not good, that it is bad, in fact, before—in other words, the burden of proof is now on EPA to prove that it is not harmful or that it is harmful. You don't have to prove that it is not.

Dr. GLASS. That's the way TSCA is written, yes.

Mr. VOLKMER. Yes.

Dr. GLASS. Again, I would say if my company were in that sort of a situation—I think most companies in our industry would not just go ahead and do a field test without any Government approval. I think under these circumstances if we had developed the type of organism you mentioned, we would certainly meet with EPA to determine if this would be subject to the R&D exemption.

Mr. VOLKMER. Before we go vote, Mr. Chairman, could I ask just one quick question?

Mr. VALENTINE. Yes.

Mr. VOLKMER. If there was a requirement under Federal law that before any company could perform an environmental release, a release into the environment of a genetically engineered product, that you would have to have liability insurance, what would that do to your company?

Dr. GLASS. I'm not the one in my company that handles insurance, so I am answering from a somewhat incomplete knowledge. We have not had a great deal of problem getting the insurance that we would need for our operations to date. Since we are not selling products of any importance, I don't believe we have product liability just yet, product liability insurance, so I honestly don't know.

Mr. VOLKMER. Thank you very much, Mr. Chairman.

Mr. VALENTINE. Gentlemen, we have some other questions. We have quorum call and we have to rush now to get over there, and then there is a recorded vote after that. Can you conveniently come back here, say, 1:30?

[Whereupon, at 12:25 p.m., the hearing was adjourned for the luncheon recess to reconvene at 1:30 p.m.]

AFTERNOON SESSION

Mr. VALENTINE. We will proceed with the questions.

I would like to ask this question of either or both of you gentleman. USDA does not require that it be notified of the release of genetically engineered plants into the environment unless those plants are known to be threats to agriculture; EPA requires that it be notified of the use of all genetically engineered organisms. If our aim is to have a uniform policy between the two agencies, does H.R. 4452 accomplish this, in your opinion?

Dr. Glass.

Dr. GLASS. It certainly is desirable to have consistency between the agencies. I will go one step further and say that we certainly have no objections, at the very least, to a notification requirements before one wants to put a genetically engineered organism of any sort into the environment.

As I have said in our testimony, though, I believe that H.R. 4452 goes a couple of steps too far in terms of instituting a highly complex permitting scheme that would adversely affect the very initial small-scale field tests, and also its inflexibility in being locked into legislation. But, yes, there really ought to be consistency throughout the Federal agencies.

Mr. VALENTINE. Would you be in a position, either one of you—I don't want to ask an unfair question, I really don't, but we seek to address a problem that some members of the Congress see as one of the biggest problems that we face—would you be in a position to address in writing what changes you think might be made in this proposed legislation to make it to continue so as to not interfere with the what aim is, and address some of these problems that you regard as unduly restrictive?

Dr. GLASS. Generally speaking, I addressed some of those issues in my written statement. Also, as I testified, we are not in favor of passage of the bill, and for that reason I did not go so far as to suggest specific changes in a piece of legislation that we would rather not see enacted.

Mr. VALENTINE. Are you saying, that in your judgment, the legislation which is on the books now is adequate to deal with the problem?

Dr. GLASS. The legislation is, yes. As I think I said earlier, and as was discussed this morning, in certain instances there might be cases where the regulations might be better drafted to cover up some of the potential gaps. But, yes, we would prefer not see new legislation.

Mr. DOYLE. Mr. Chairman, we differ with that view, we think legislation is needed at this time. We think H.R. 4452 is a beginning step in that process and as I said in my statement we cannot support the bill as drafted now, but we would certainly be willing to work with the committee in reformulating that or another bill with some of the suggestions that we made today testimony.

Mr. VALENTINE. Dr. Glass, do you believe that the Federal Government should require that all companies which apply for permission to perform environmental releases have liability insurance?

Dr. GLASS. No, I do not.

Let me just say before elaborating on that, I am not a lawyer and I am not 100 percent familiar with many of the environmental statutes and other relevant laws. But to my knowledge, I don't believe that there are any other relevant statutes under which any other manufacturers of any other types of products are required to have product liability insurance. So we would feel, therefore, it would be most unfair to single biotechnology for such treatment.

Mr. **Valentine**. And you don't think that because of the nature of this beast that it should be treated differently?

Dr. **Glass**. No, as I have said in the testimony, we do believe that the products of recombinant DNA and the new biotechnology are not different from the products that have been produced by the classical genetic engineering techniques that have been used in agriculture for a decades and centuries. I will just point out, too, that currently makers of microbial pesticides, of which there are something like 13 registered by the EPA, these companies have field tested and are selling these projects, and don't believe that there were specific product liability insurance requirements on these companies. Those products are excellent models for the types—those are all mutated or naturally isolated organisms, of course—and they are excellent models for the types of agricultural microorganism that will be introduced using recombinant DNA. They are very analogous products.

Mr. **Valentine**. Of course, the reason for the requirement of liability insurance anywhere—and most states do, I believe, now have compulsory liability insurance for the operation of motor vehicles on public highways—and there is a theory behind all of that, of course, is to be sure that there is a pocket, there is some way that the corporation who causes injury can respond in damages, and the fear being that without liability insurance, which, of course, for one reason or another is getting more difficult to obtain, that you might have great harm caused by a corporation which was insolvent, or which was so structured that it would not be able to respond in damages.

Mr. Doyle, do you have any answer to that?

Mr. **Doyle**. Mr. Chairman, thank you. I think the liability question is a very important one. I think one of the first steps that needs to be taken here is for the committee to poll some insurance firms as to what they think about this particular question and how would they approach writing liability policies for these particular organisms that will be released. Then we have a base of information, I think, to go forward on and start thinking more seriously about how a liability provision, if it were to be drafted into the legislation, would be crafted, but I think that would be an important first step.

There was a remark made about no such provision being in other legislation or to your knowledge not. I think there are some analogous situations. One particular law that I am familiar with is the Federal Service Mining Control and Reclamation Act to the strip mining law. There you have a situation where there is a bonding provision where the operator has to put up a bond in terms of reclamation. And there may be some utility in looking at that concept as maybe a kind of protection or bonding proviso that may be another mechanism that could be explored in conjunction with the liability question.

But I do think that first and foremost we should go to the industry and ask them about this question.

Dr. **Glass**. If I might, Mr. Chairman, with all due respect, Jack, I am not sure it is an appropriate analogy to compare surface strip mining of large acres of land which would effectively ruin that land for future uses, comparing that with very limited scale field testing of micro-organism pesticides or genetically engineered organisms.

Mr. Doyle. No, well, there are public health and safety questions involved with strip mining, just as there are with the release of recombinant organisms or other organisms made through biotechnology techniques. I think the question is public health and safety, and the risk factor.

I am in no way trying to equate strip mining with the release of recombinant DNA. In fact, my own view would be that there is more risk involved in certain organisms than there is with strip mining, because you can reclaim a site and you can prevent imminent damage from occurring on reclamation sites.

Mr. Valentine. OK.

Can you go out the same door, or will you have to go out different doors?

Dr. Glass. Jack and I have shared a panel before, several times.

Mr. Valentine. Thank you very much, both of you.

We will hear next from Dr. Jack Moore, Assistant Administrator, Office of Pesticides and Toxic Substances, Environmental Protection Agency.

STATEMENTS OF STEVEN SCHATZOW, DIRECTOR, OFFICE OF PESTICIDE PROGRAMS, ENVIRONMENTAL PROTECTION AGENCY; AND ANNE HOLLANDER, BIOTECHNOLOGY PROJECT MANAGER, OFFICE OF TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY

Mr. Schatzow. Good afternoon, Mr. Chairman. My name is Steven Schatzow, I am Director of EPA's Office of Pesticide Programs. Dr. Moore is hung up with a markup with the House Agriculture Committee, and regrets that he is not able to be here.

Mr. Valentine. Is he hung up or strung up?

Mr. Schatzow. Both; hung and strung, as best we can tell from this morning.

We regret that we are sending in the second team, but we will do the best we can.

As I said, I am the Director of the Agency's Office of Pesticide Programs. With me is Anne Hollander, who is from the Agency's Office of Toxic Substances, and is one of the resident gurus on biotechnology.

Understanding the operating rules today, I would like to submit our testimony for the record.

Mr. Valentine. Yes, let us have it; or if you have that will appear in the record. You may summarize it or proceed anyway that you deem appropriate.

Mr. Schatzow. I know that the committee will have a number of questions, so I what I would do is make a few general points, and then take questions.

We believe that with the type of two major statutes that we have to implement at EPA, FIFRA, the Federal Insecticide, Fungicide, and Rodenticide Act, as well TSCA, that there is existing authority which is adequate for the regulation of genetically engineered and genetically altered organisms, both that are pesticides and those that are not pesticides. So the agency does not believe that there is a need to provide for additional specific authority that relates to genetically engineered organisms.

I think the second general point that I would like to make is that in this emerging scientific area there is a need for flexibility as the science develops, and particularly as the regulatory science develops. We have already had experience now under FIFRA with notifications from about 10 different institutions and companies, about desires to field test. We have gone through a series of changes in the way we look at these organisms in terms of the kind of data, in terms of how comfortable or uncomfortable, what our level of review needs to be. So it seems to me very important that we maintain the ability to make case-by-case decisions within a general statutory framework as we gather this experience. It seems to me that trying to legislate with specificity, detailed ways of going about this process, would not be a good idea at this point.

The third point I would like to make is that we are dealing with two very different statutes when we talk about the difference or the contrast between FIFRA and TSCA. FIFRA is an explicit licensing statute. It requires that before any pesticide can be sold in this country, offered for sale, or used, it must be registered and approved by EPA. It also has a provision for experimental-use permits in which a permit is required prior to field testing.

TSCA is obviously a very different kind of statute. It is not a licensing statute. It is a premanufacturing notification statute and operates through rulemaking without licensing.

I think that the issue that is raised, the major issue that is raised in terms of the bill before us is the question of whether that is an appropriate mechanism, that kind of premanufacturing notice, as opposed to a permitting mechanism. I think there a lot of things, since I operate under the FIFRA program, which is a licensing program, that make a licensing program very attractive. But I guess my feeling is that if we want to take on the issue of changing TSCA from a premanufacturing notice statute to a licensing statute, let's take on that as the issue, and not take it on as it applies to some subset of particular chemicals or organisms.

In other words, again, I think probably our strongest feeling throughout this is that what we really don't like is the notion of viewing genetically engineered micro-organism as somehow so different and so unique from the other kinds of chemicals as well as micro-organisms that our agency is dealing with on a day-by-day basis.

There are three specifics of the bill that I would like to mention. We have got, as I suggest, a variety of problems with the bill, they are summarized in our testimony but there are three I would like to mention.

One is the definition of a genetically engineered organism. We don't feel it is an appropriate definition. It is a limited definition, which would only cover certain genetically engineered organisms. And, again, by distinguishing between genetically engineered organisms and nongenetically engineered organisms, we think there is a very false distinction being made in many cases.

We think that the kinds of risks that may be presented by microorganisms are not fundamentally related to the question of whether they are genetically engineered or how they are genetically engineered. It is the characteristics of the organisms. And there are a variety of nongenetically engineered micro-organisms that may present significantly greater risks because of their characteristics, than genetically engineered organisms.

The second point I would like to make about the bill is in terms of the permitting process, what we view as the complexities and ambiguities of the three-stage permitting process. As I mentioned, under FIFRA we have a fairly clear two-stage permitting process: experimental-use permits, for field testing and then registration for commercial products. We think that if any kind of permitting system is developed under TSCA, and, again, we think that if it is, that it should be for all of TSCA, and not limited to genetically engineered micro-organisms, that one should go to that type of a two-phased system, as opposed to the three-phased system which is in this bill.

The third major concern I would like to mention is a concern about the biotechnology advisory board which is proposed in this bill. The provision specifically says that this biotechnology advisory board would have to review every application, every notification submitted to the agency. And, again, this is what I mean when I talk about the kind of inflexibility of the bill.

We have been operating—to give you a parallel—under FIFRA, with a scientific advisory panel, and we have been taking the applications that we receive and having them reviewed by a subnel of that scientific advisory panel. I would hate to be in a position where every thing that came in had to be reviewed by such a panel.

Again, as we gain more and more experience, it seems to me that it would be very appropriate to say for a number of different applications that come in to us, we don't think that needs a review, we think that is similar enough to something that panel has already looked at, or we think it is similar enough to something which we have already licensed which is a natural micro-organism. Again, I think that point goes to the need for flexibility.

I think I will stop at that point, Mr. Chairman, and try to answer any questions. I think I have summed up what I think are our fundamental concerns about the bill, and about the whole approach of singling out genetically engineered micro-organisms and, in fact, a subset of genetically engineered micro-organisms for very specialized treatment.

I think it is true, and it is consistent with our experience under FIFRA, and it will be consistent as we develop our regulatory experience under TSCA that in the beginning as we get more, as we start out with applications in terms of genetically engineered micro-organisms, we will be giving them more careful scrutiny than we give a variety of other chemicals. But we can give them that kind of scrutiny within the existing statute and with the flexibility that does not subject all of them to the same level of scrutiny or the same level of intensity for all time.

Thank you.

[The prepared statement of Mr. Schatzow follows:]

STATEMENT OF STEVE SCHATZOW, DIRECTOR, PESTICIDE PROGRAMS, U.S. ENVIRONMENTAL PROTECTION AGENCY

Good morning. I appreciate your invitation to provide EPA's comments on the Biotechnology Science Coordination Act of 1986. I would like to begin by giving brief answers to the four questions you asked me to address in your letter of invitation. Then my testimony will expand on those comments.

First, in response to your question concerning Agency authority, the Agency believes that the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act are appropriate and sufficient for regulation of genetically engineered microorganisms released to the environment and used for purposes falling under the two acts.

Second, the major differences between the Biotechnology Science Coordination Act and EPA's policies are the emphases in the Act on a permitting system and on genetically engineered microorganisms. The permitting provisions are reasonable alternatives to some of the current provisions of TSCA, but they are not necessary and the advantages they provide are not unique to genetically engineered organisms. Further, the Agency does not believe there is any scientific justification for singling out genetically engineered organisms for special legislative action.

Your third question concerned types of genetically engineered organisms that should be exempted from strict standards of review. The Agency's policies will provide for different levels of scrutiny of microorganisms depending on the potential for exposure, possible adverse effects, and degree of uncertainty about risks. Some genetically engineered microorganisms will be subject to full, detailed reviews, while others will be subject to more abbreviated notification and review procedures. It is important to note that most microorganisms will have a higher level of scrutiny than chemicals because they will be subject to review before any release into the environment.

Fourth, in response to your question about changes in the act to facilitate regulation, the Agency believes that this legislation is not needed, that as written it is too inflexible and would not give the Agency sufficient discretion in a number of areas, and that its focus solely on genetically engineered microorganisms is unjustified. The Agency finds that many of the specific provisions, as currently drafted, would not be beneficial for EPA, the regulated industry, or the general public.

To explain the Agency responses to these questions, I will make some general observations about the perceived need for new legislation for genetically engineered organisms. Then I will provide comments on specific provisions of the act.

Let me say that EPA agrees with many of the statements made by Congressman Fuqua when he introduced this bill on March 18, 1986. Specifically, EPA agrees that biotechnology products must be allowed "to travel a clear and certain path from the laboratory to the marketplace." The Agency also believes that the regulatory system must be "fair, predictable and informed." Where we part company with the drafters of this legislation is in the assumption that existing legislation will not accomplish these goals. It is for this reason that we must oppose this bill.

Several Federal agencies are about to issue a governmentwide policy that we believe does provide fair, predictable and informed regulation for biotechnology products. It relies on a number of existing laws implemented across several agencies. We believe this approach is appropriate, because the biotechnology industry will produce many diverse products and that these products should be regulated as other products in the United States are regulated—according to their use.

In addition to EPA's conviction that new legislation is not necessary in this particular case, we believe that appropriate policies can be and will be implemented under existing statutes much more expeditiously than through new legislation. Once it has been enacted, new legislation may take many hears to fully implement. Consistent policies are needed now rather than later to ensure against possible risks and to help reduce the regulatory uncertainty for this important new industry. Adopting new policies under existing laws, as EPA and other agencies have done, also provides for considerable flexibility to adapt as necessary to the changing industry and the evolving science of biotechnology. Statutory changes would, in contrast, be relatively difficult to alter even if scientific developments suggested it were appropriate to do so.

The rest of my remarks will focus on the Biotechnology Science Coordination Act, especially Articles III and V of the act. Article III would amend the Toxic Substances Control Act to include specific provisions for genetically engineered organisms. Article V would limit EPA's ability, under the Federal Insecticide, Fungicide and Rodenticide Act, to give special consideration to genetically engineered organisms being tested at certain institutions.

Under TSCA, the Agency already has broad and adequate authority to review microorganisms. The Agency does not believe that this act is necessary to clarify or establish TSCA's applicability to microorganisms. In fact, we are concerned that the scope of the amendment would be less, with its focus on a narrow definition of generic engineering, than the broad authority we have described in the Agency policy statement. In addition, we have concerns regarding the inflexibility and lack of Agency discretion in several of the provisions and to the potentially burdensome nature of the proposed permitting system.

To explain further, one of the EPA's most significant concerns is the specific and narrow focus of this act on "genetically engineered" organisms, as defined in section III(b) of the act. This definition limits the scope of the amendment to not only a subset of microorganisms, but also a subset of the organisms generally defined as genetically engineered.

We do not believe it is prudent to group all genetically engineered organisms into a single category of regulatory concern. EPA has, for example, developed different levels of scrutiny of microorganisms that reflect differences in their potential for widespread exposure, potential for adverse effects, and uncertainties about risk. Thus, our approach differs from the approach under Title III, which would establish a statutory amendment for all genetically engineered organisms, as defined in the act, independent of other considerations. Certain nonengineered organisms may be both new and risky, while certain engineered organisms may be neither. Yet the proposed legislation would not recognize these distinctions, and would tend to perpetuate the misconception that all genetically engineered organisms are inherently of sufficient concern to merit a very high level of federal oversight.

We certainly understand and acknowledge that there are public concerns about genetically engineered organisms, and we intend to use our authority to monitor these organisms carefully as we obtain additional information about their possible risks. Still, we believe our regulatory decisions and data requirements should be based on case-by-case assessments of products, and that we should avoid establishing legislative mandates for certain classes of products unless there is established justification for doing so. In the case of this amendment specifically, we think it would be better if it applied to microorganisms in general, rather than genetically engineered organisms specifically.

In addition to being too inflexible, the definition of "genetic engineering" provided in Article III (b) of the act presents some scientific problems. The general difficulty is that the definition does not approximate most peoples' understanding of what is meant by the term "genetically engineered organisms." Organisms "altered to contain genetic material from more than one taxonomic genus" are merely a subset of all genetically engineered organisms, and it is technically confusing to make them appear, by definition, to be the same thing (even though EPA agrees that organisms from different taxonomic genera constitute one of the areas currently deserving regulatory attention). Further, the list of organisms in this definition appears to omit some important microorganisms; blue-green algae, algae, mycoplasmas, and protists do not appear to be included. Another technical problem is that the concept of taxonomic genus does not apply to viruses, so that application of the definition to viruses is unworkable.

Next I would like to comment on the three-step permitting process that this act would establish under Title III, subsections (d) through (f). The Agency believes that it is a major decision to make TSCA a permitting and registration statute and recognizes that there are advantages and disadvantages to such a change. It could allow EPA to review organisms subject to TSCA at different stages of their use, not just at the point of initial release or commercial use. This seems reasonable from a health and safety perspective, and it is also more consistent with other statutes that provide oversight for biotechnology and and other consumer products, such as the Food, Drug, and Cosmetic Act, and the Federal Insecticide, Fungicide, and Rodenticide Act. Second, a permitting system might simplify and reduce resources requirements for the Agency when it needs to obtain additional data; there would be less need to go through lengthy negotiations or rulemaking procedures for each different organism. Finally, the legal findings that would be necessary to grant, waive or withdraw permits, described in subsections (d) through (f), appear to be worded in a way that would provide a reasonable level of Agency discretion to make decisions that protect the health and welfare of American citizens. Nevertheless, having pointed out these advantages, I must reiterate my concern that these sections focus on "genetically engineered" organisms rather than organisms or chemicals in general, and that we believe this focus is unjustified.

The Agency believes that the three-step permitting system outlined is needlessy burdensome and lacks clarity. For example, we do not see the advantages in a two-step precommercialization permitting process. In addition, it is not clear what the criteria are for moving from one step to another. We would suggest that the two-step process implemented under FIFRA is an appropriate model, that is, a process requiring permits at the experimental and commercial use stages. Furthermore, we believe the Agency would have the discretion to develop a permitting and registration system through regulations rather than have them defined in the legislation.

The list of required information that must be submitted with all permits (described in Article III, subsections (d) through (f) of the act) appears reasonable, given current knowledge and understanding of risk assessment for genetically engineered microorganisms. However, the Agency again believes that the application of these requirements to genetically engineered organisms as a group is misguided. I have also mentioned the problem of inflexibility that is inherent in putting detailed requirements in a statute. EPA's experience suggests it would be preferable to give the Agency authority to obtain data readily and as necessary, on a case-by-case basis (including but not limited to the data described in this section). Information requirements should be continuously updated over time to keep pace with scientific developments, and they should be applied on a case-specific basis to those products for which the information is necessary.

While the Agency acknowledges the desirability of public awareness, EPA does question one set of requirements in subsections (d) and (e) because they appear unworkable. These are the requirements that applicants place announcements in local newspapers once a week for 4 consecutive weeks, prior to releasing, using or distributing any genetically engineered organism in that location. These provisions do not seem reasonable when products are to be used or distributed in numerous locations, and when they have been previously tested in small-scale field trials. EPA believes that the goal of public notification would be well met if this requirement applied to initial use permits for environmental release experiments, but not to all expanded use permits.

EPA also has reservations about the Biotechnology Advisory Panel, as described in Title III, subsection (h). As you may know, we have already chartered a Biotechnology Science Advisory Committee [SAC] to provide the Agency with technical advice on biotechnology issues. The SAC is chartered for 2 years, extendable as necessary. We believe the SAC will serve the same purposes as the proposed Biotechnology Advisory Panel, but here again, we question the advisability of turning a current need into a permanent fixture of TSCA. Over time, the focus of the committee might need to change, or the need for the committee might disappear altogether.

There are also several difficulties with specific provisions of subsection (h). As written, the Biotechnology Advisory Panel is intended to "review and assess applications for all types of permits" authorized under Title III. Within a few years, this requirement could easily result in the committee sitting in session every working day of the year. If it were mandated at all, it would be preferable to allow EPA to use the committee to address particularly difficult or novel scientific issues, rather than requiring its involvement in every permit. Also, the proposal gives the committee the responsibility to "prescribe data submission requirements and risk assessment protocols for permit applicants," in effect authorizing the committee to make decisions which, earlier in Title III, are stated to be the responsibility of the EPA Administrator. This confusion would be elminated if the committee were advisory only.

The requirement in section III(g), to report to Congress every 6 months, seems unnecessary. EPA is always willing to provide information on the number of permit applications, final actions taken, pending actions, and other information that any Congressional committee desires. Furthermore, because Congressional interests and responsibilities shift between various committees over time, it is not clear to whom this information would be sent or whether it would be useful on an indefinite basis.

Section III(k) states that EPA shall, within 2 years of enactment of this section, "prescribe and publish regulations to govern . . ." the permitting sytem. Based on experience, this 2-year period seems unrealistic. Issuance of regulations is a lengthy process, requiring significant resources internally as well as adequate time for public involvement and comment prior to issuance of regulations. Also, it is not clear how EPA would be expected to operate during the intervening period before regulations were promulgated. Would the policies EPA is about to publish as part of the overall Federal approach be in effect, or would interim permitting procedures need to be established?

Article V of this act would amend section 5(g) of the Federal Insecticide, Fungicide, and Rodenticide Act, such that the Agency could not give special consideration to "genetically engineered" organisms being tested at certain agricultural research agencies and educational institutions. The Agency reiterates that FIFRA is adequate to regulate genetically engineered microbial pesticides and that no amendments to the act are needed. I point to the Agency's recent reviews of genetically engineered pesticides as evidence of FIFRA's adequacy. I believe Congress should maintain EPA's discretion to make decisions on experiments involving "genetically engineered" microorganisms, based on current knowledge of the level of risk and on case-by-case assessments of data.

Finally, I would also like to comment briefly on Title II of the act. Title II would establish a biotechnology science research program in OSTP. I share the concerns expressed by Drs. Kingsbury and Johnson with respect to establishing biotechnology research priorities. I feel strongly that individual Federal agencies such as EPA, USDA, and FDA, are best suited to establish research priorities in biotechnology and that research activities must be carried out in the context of the individual Agency's mission. Research needs will, in certain cases, overlap, and in these situations a coordinated research agenda would be appropriate. The Biotechnology Science Coordinating Committee will be the appropriate forum to discuss overlapping science and research issues.

Thank you for the opportunity to testify. I would be happy to answer any questions you may have.

Mr. VALENTINE. Thank you very much.

Ms. Hollander, do you have anything that you would like to add to that?

You are just here to help answer the questions?

Could you give us your version of a definition that would be more suitable; I don't mean now?

Mr. SCHATZOW. I believe that we could give a broad definition of what is a genetically engineered micro-organism. Again, I think the problem that we have with that is suggesting that things that uniformly fit within that definition are to be treated differently than a variety of other micro-organisms.

Mr. VALENTINE. Specifically, of course, the definition which would be better in your judgment for identifying organisms that should be reviewed before release?

Mr. SCHATZOW. Well, the approach that we are pursuing under FIFRA and will be pursuing under TSCA will be to require advance notification for environmental release of all genetically altered or engineered micro-organisms, but to be able to differentiate, depending upon the characteristics of the micro-organism as to the kind of review that we will undertake and as to the kind of information that will be necessary to support an application for field testing.

Mr. VALENTINE. Aren't they exempting some now?

Mr. SCHATZOW. Under FIFRA at this time, under our interim policy of October 1984, we are requiring that the agency be notified before there is any environmental release of any genetically altered organism or any nonindigenous micro-organism proposed for environmental release.

Mr. VALENTINE. Are you expecting to change the definition?

Mr. SCHATZOW. No, not in terms of FIFRA, we are not expecting to make any change. We are, again, proposing planning to differentiate in terms of the levels of review and the kind of information that is required depending upon the characteristics of the micro-organism. But what we intend under FIFRA is to be notified and to review every genetically altered micro-organism before it is environmentally released.

Mr. VALENTINE. Well, FIFRA only covers pesticides, doesn't it; it involves only microbes?

Mr. **Schatzow**. That is right, only those microbes that have pesticidal properties; that is correct.

Mr. **Valentine**. Title II of the proposed legislation would establish a joint industry/Government research program to facilitate the development and regulation of biotechnology products under the Office of Science and Technology Policy, in particular this research program would promote scientific research which would enable regulatory agencies to assess the risks of environmental releases more accurately and more comfortably. What are your views concerning such a joint industry/government research effort?

Mr. **Schatzow**. I think there are aspects of that we would be comfortable with. We really haven't taken the lead in terms of our testimony. I think there are a number of the other people that have testified in terms of the National Science Foundation and OSTP that are probably more appropriate to respond to that general issue. I think a lot of the issue that we are dealing with in terms of environmental release and the potential impact, in terms of micro-organisms particularly, may be of greater concern to EPA than they may be to a variety of other agencies, and it may be that we would have to maintain the lead for much of that research.

Mr. **Valentine**. Would it be appropriate, in your opinion, to locate this program in Office of Science and Technology Policy.

Mr. **Schatzow**. I think if there were going to be a general program of that type, that would be one of the most logical places to locate it.

Mr. **Valentine**. Would the biotechnology science research program be appropriate, in your opinion, to commission scientific research in the areas of risk assessment and risk management?

Mr. **Schatzow**. Again, we really haven't gotten into the details of looking at that aspect of the bill. Our focus has been particularly in terms of the impact of this bill on FIFRA and on TSCA. I think clearly there are a series of generic issues where it is important to have coordination both in terms of policy issues as well as science issues.

Mr. **Valentine**. FIFRA requires that data be submitted to EPA before a permit is issued for the use of microbial pesticides. Under TSCA a company simply notifies the agency that it wants to market a product, for example, an organism that could be used in hazardous waste cleanup. Since EPA is charged with protecting the environment, doesn't it seem reasonable to have the same degree of prospective scientific review for organisms intended to be used in the environment under both FIFRA and TSCA?

Mr. **Schatzow**. As I commented earlier, I think that is a real important question, and a very good one. I have operated under the FIFRA statute for the last 2 years and see some very strong benefits to having a licensing statute. I don't know that the agency would object to the conversion of TSCA into a licensing statute.

What the agency would strongly object to, however, is carving out a certain subset of micro-organisms and subjecting them, and only them, to this kind of a licensing statute.

Mr. Volkmer?

Mr. **Volkmer**. I have several questions. I guess we could stay with TSCA just for a little bit, and the present guidelines, and what you may know about it in the present circumstance, where we are right now.

As I understand where we are right now, without the guidelines and with present regulations, under TSCA and the present statute, that we merely have a reporting requirement when we have a release of micro-organisms; is that correct or incorrect?

Ms. HOLLANDER. That is correct.

Mr. VOLKMER. That is correct, and therefore I could field test a genetically engineered intergeneric micro-organism, microbial without any notification to EPA?

Ms. HOLLANDER. That is correct.

But we have in our proposed policy that was issued in 1984, we made it clear that we expected people to notify us if they intended to do that. We have also paid pretty close attention to the kinds of development in the field of the things that would be subject to TSCA, and we really don't think that there are any things imminent with the exception of, possibly, two companies that did notify us voluntarily that they were thinking of field testing, and neither of them has.

So, although it is true that such requirements are not in place right now, we don't think that there are any organisms that would fall under the case you are talking about.

Mr. VOLKMER. Then EPA has not had a formal application for licensing for any microbial or bacterial product as of this time; is that correct?

Ms. HOLLANDER. That is correct.

Mr. VOLKMER. But we still at this time—now you plan to correct that, as I understand, by rulemaking; is that not correct, through TSCA?

Ms. HOLLANDER. Yes; we anticipate establishing a requirement so that new micro-organisms and also pathogens, we will have to be notified of those before they are released under either premanufacturing notification or as a significant new use. We also expect that a lot of other organisms we will correct by rulemaking, ask to be notified of before release.

Mr. VOLKMER. Now, I have notified you, I go ahead and do the field test?

Ms. HOLLANDER. Well, you have to notify us beforehand——

Mr. VOLKMER. I know. I have notified you, and I tell you I am going to do a field test 6 weeks from now; what are you going to do about it?

Ms. HOLLANDER. You have to give us 90 days if it is a new organism, or if it is a significant new use——

Mr. VOLKMER. I have given you 90 days, now what are you going to do about it?

Ms. HOLLANDER. At that point, during the 90 days, and probably before the days even begin, we will start considering whether there are potential risks, because if you are a company you will probably come into us long before you submit PMN and conduct some sort of prenotice consultations with us. During the 90 days we will conduct that review, and at the end of it would say there is going to be a very good chance that we will ask for additional data. And when the data come in and we have had a chance to review them, at that point the field test might proceed if we say that it can——

Mr. **Volkmer**. What if you have reservations about micro-organism and field tests because maybe something wasn't done sufficiently in the lab tests; are you going to stop me from doing the field test?

Ms. **Hollander**. I think we would, we can——

Mr. **Volkmer**. Under what statutory authority?

Ms. **Hollander**. I believe it is section 5(e) of TSCA, if we decide that there are insufficient data or insufficient information, and potential for either harm or widespread exposure, we can require additional data. That can be done under rulemaking. Generally, rather than going through the rulemaking procedures, companies prefer to do the testing that we expect them or want them to do.

Mr. **Volkmer**. In other words, you are relying basically on the good will that the company wants to have with EPA and continuing relationship, so they won't do anything wrong.

Ms. **Hollander**. I think in many cases it will work that way. If the company decides that they don't want to submit the data, we have other mechanisms to obtain it and to prevent the field test from occurring.

Mr. **Volkmer**. Could you bring injunctive relief to stop me if I went ahead and had done it anyway?

Ms. **Hollander**. Probably; it would depend on making the necessary finding. But yes, we have authority under TSCA.

Mr. **Volkmer**. Even under the exemption, the 10-acre exemption?

Ms. **Hollander**. There is no 10-acre exemption under TSCA.

Mr. **Schatzow**. I think that the 10-acre exemption that you are referring to, Congressman, is under FIFRA.

Mr. **Volkmer**. All right.

Mr. **Schatzow**. That is in the rules and it is not in the statute, and we have amended it through our interim policy.

Mr. **Volkmer**. Do you have to obtain a rule in order to require me to provide additional data under TSCA?

Ms. **Hollander**. Yes; we may have to if you don't agree to do it when we ask——

Mr. **Volkmer**. How long is that?

Ms. **Hollander** [continuing]. Our experience is that generally people go along with it because they don't want the stigma.

Mr. **Schatzow**. The point, Congressman, I think, is that we have the ability to enjoin the testing during that period of time, if we are forced to go through a rulemaking exercise to gather that data. I don't think there is something that falls within the cracks.

I think Anne is right, that usually one can expect that the company will do the testing, which is a much more rapid way of going ahead with the experiment, as opposed to forcing us to go through a rulemaking to actually require the testing. But if we have some significant risk issues and we don't have adequate information to resolve them, we do have the ability to stop that experiment from taking place.

Mr. **Volkmer**. On the basis the microbial release would be injurious to health, safety, or what?

Ms. **Hollander**. Either that finding, or that there will be significant exposure.

Mr. **Volkmer**. Just significant exposure to something that is not harmful?

Ms. **Hollander**. Yes; section 5(e) says that you have to make—basically the finding is—this isn't the exact wording—we have to have insufficient data which we can determine and then either finding of will present hazard, or will significant exposure. With the living organism we feel we won't have too much trouble making that finding.

Mr. **Volkmer**. So you just have to show exposure, not that the exposure would cause any difficulty; you don't have to prove that?

Ms. **Hollander**. That is correct.

Mr. **Volkmer**. All right.

Mr. **Schatzow**. Obviously, in many cases we might be in a situation of not knowing what the hazard would be and that is the reason we are requiring the additional testing.

Mr. **Volkmer**. All right.

The last thing down the line on this. Now, I am doing noncommercial R&D—OK—now can you stop me by an injunction?

Ms. **Hollander**. No; all chemical substances under TSCA are excluded. Noncommercial is excluded in the statute.

Mr. **Volkmer**. So if I was a university professor up here and had a grant or arrangement with a chemical firm, and I was just doing some basic research, not looking to commercial application, and I wanted to go out and test whatever I had done, I am exempt?

Ms. **Hollander**. That is generally correct. There are two points I would like to make, though. One is that that exemption does not apply under section 7, which is if the finding of imminent hazard were to occur, EPA could then, if we made that finding, we could——

Mr. **Volkmer**. You would have to find that it was an imminent hazard, though.

Ms. **Hollander**. Right. The other point is that——

Mr. **Volkmer**. You have to have the data to do that from.

Ms. **Hollander**. We might or might not. It would depend, certainly, on a specific case.

The other point, though, is that we believe that most noncommercial research will be handled by other parts of the Federal Government which do review, regulate, and have various mechanisms for overseeing noncommercial research. For example, this is what the National Institutes of Health has been doing for more than a decade. And also the Department of Agriculture has authority to do that.

Mr. **Volkmer**. They have for their funded research?

Ms. **Hollander**. That is correct.

Mr. **Volkmer**. And all you have for non-Government funded research is the biosafety committees at the various universities, you do not have a Government agency regulating that. We just had testimony this morning on that. That is some of the things that concerns us, some of us.

EPA recently suspended the EUP for field testing for ice minus, and AGS, requiring additional tests. Now let's assume that we have the new guidelines in effect, which I don't know what they are, but let's assume that we had them in effect, would AGS have been required to have the release of this ice minus reviewed by EPA since it is only a genetic deleted product?

Mr. SCHATZOW. Yes; as I stated before, the fundamentals that were articulated in our interim policy are the same in terms of what is going to be in our final policy. We are saying is that for all genetically altered microbes, as well as all nonindigenous natural microbes, EPA will have to be notified. The level of review will vary depending upon the characteristics of the micro-organism, but EPA will have to be notified in all cases.

Mr. VOLKMER. Now, you have got the parent or base bacteria, as I understand, in the advance genetic sciences experiment, that is nonpathogenic; is that correct?

Mr. SCHATZOW. That is right.

Mr. VOLKMER. Without the deletion; is that correct?

Mr. SCHATZOW. That is correct.

Mr. VOLKMER. Now, all you are doing—all they are proposing to do is to delete a gene from a nonpathogenic; now what type of review are you going to require under the new guidelines, a notice, that is all?

Mr. SCHATZOW. Well, I think what we have required, and what we will continue to require, is notification in all cases. Based on that notification we will be making a determination as to whether an experimental-use permit is required.

I think what we are working out now is in terms of dividing up, trying to divide up generally the magnitude of the notification, trying to separate genetically altered micro-organisms into categories where, I think, we will be requiring more detailed notification for some, and some less detailed notification for others. But in all cases we will be requiring notification. And in all cases, depending upon the data submitted to us, we will be making determinations as to whether additional information is required and whether an experimental-use permit is required.

Mr. VOLKMER. Well, as I understand it, even under the proposed guidelines—correct me if I am wrong on this—from what I have been furnished, the policy is going to be even under FIFRA, when it is less than 10 acres, it is a genetically engineered micro-organism, but it is formed by genetic engineering other than intergeneric combinations and nonpathogenic source organisms, that the only thing would be an abbreviated review?

Mr. SCHATZOW. Well, I don't know what you mean, the only thing would be an abbreviated view. It will require an advance notification, a certain amount of information to be given to the agency, and the agency to make a determination as to whether more information is necessary and whether an experimental-use permit is required.

Yes, I think you are talking about certain types of micro-organisms that we think probably pose less risk and, therefore, we start out by saying, we think we can do a more abbreviated review. We think we need less information. And we say to the people who have those kinds of micro-organisms, give us this initial group of information, we will then make a determination as to what we think the relative risk is and whether we need more information, and whether we can say at that point, you will need an experimental-use permit, or you won't.

The thing that I keep trying to emphasize is that under our existing interim policy, and under anything that may or may not get into the Federal Register in the next few weeks, we will be requiring advance notification before there is any environmental release. And there cannot be any environmental release unless EPA approves, either by approving an experimental-use permit, or by telling the applicant that an experimental-use permit will not be required. It is the level of the scope of the review that may differ.

Ms. HOLLANDER. Can I elaborate on that a little bit?

Mr. VOLKMER. Yes.

Ms. HOLLANDER. I think one thing that might be important to understand is that all of these organisms will receive a higher level of review, or review earlier in the process of their development, than would a normal chemical pesticide. But within this category of all receiving higher and sooner level of review, some will not be subject to an extremely high level, they will be subject to this—you are calling it—"abbreviated review."

Mr. VOLKMER. What if the information as to the data that you are furnished by XYZ corporation is incorrect?

Mr. SCHATZOW. I don't know what you mean as incorrect?

Mr. VOLKMER. Lab work not properly done, even though it said it was?

Mr. SCHATZOW. Well, one of the——

Mr. VOLKMER. Ice minus?

Mr. SCHATZOW. Ice minus, this is——

Mr. VOLKMER. What do you do if it is before the EUP?

Mr. SCHATZOW. Well, what we have done recently in the case of the submissions that we received because of the experience that we had ice minus, what we did recently in terms of the submissions we received from Dr. Lindow, and Monsanto, was to do lab audits of both of those, of the data. That is something, again, generally, we have not done that in the past. And we probably would not have done it in this case, if it had not been for the experience with AGS.

Mr. VOLKMER. In other words, you are satisfied that under your interim policy, and under the new guidelines, that we are not going to have things fall through the crack in the areas of noncommercial R&D and small business products?

Mr. SCHATZOW. Anne may want to address that issue a little bit as it relates to TSCA, certainly, in terms of FIFRA——

Mr. VOLKMER. I mean TSCA.

Mr. SCHATZOW [continuing]. We have complete coverage.

Mr. VOLKMER. In relation to TSCA, not FIFRA; I am not worried about FIFRA.

Ms. HOLLANDER. The question again is noncommercial R&D and——

Mr. VOLKMER. Small business.

Ms. HOLLANDER. Small business?

OK, as I have already said, noncommercial R&D is exempt from most of the provisions of TSCA, but not section 7. We believe, generally, that it will be adequately handled by other agencies, but his exemption is not specific for genetically engineered organisms, it is for anything subject to TSCA, and that is an aspect of the law that has always been there.

The small business exemption is a different issue, this applies only to one section of TSCA, I believe it is section 8. It does say that certain small businesses are exempt from the reporting requirements of section 8. We can consider, and intend to consider further how to define small business for the purpose of biotechnology industry.

I remember hearing earlier this morning you asking a question about this. And I think most people would agree that $40 million may constitute a small business for a normal chemical company, but probably constitutes a very well-established biotechnology company.

Mr. Volkmer. Biotech/R&D company which we are having grow up—you may find quite a few of them fitting into that category.

Thank you, Mr. Chairman.

Mr. Valentine. Thank you very much.

We have, as you see, a quorum call followed by a vote, so we will just have to suspend this operation for a few minutes.

If you could stick around, we have one or two questions that either I or the real chairman would like to ask you.

[Recess.]

Mr. Valentine. We will go back to work, please.

Let me ask you this question, isn't it true that a gene deletion product could be field tested under 10 acres without a permit under these new guidelines?

Ms. Hollander. No.

Mr. Schatzow. Now, let me again try to go over that. As I stated earlier under our interim policy and under our final policy, in terms of FIFRA, the agency is going to require advance notification before there can be any field testing of any of genetically engineered or altered microorganism, any field testing of any size, any environmental release.

The scope of review and the scope of notification will vary depending upon the characteristics of the microorganism. And I do want to correct one of the things I said earlier when we are talking about the AGS experiment and the deletion product, in terms of our policy, in terms of the abbreviated review and the abbreviated notification which will apply to certain deletion products and certain nonpathogenic micro-organism. The AGS experiment itself would not have qualified for the more abbreviated review because although the AGS micro-organism was itself nonpathogenic, it was a member of a species which has pathogenic strains and, therefore, would be subject to the full notification and the full review.

But, again, let me emphasize under FIFRA, under both our interim policy and under our final policy we will require notification for genetically altered microbial pesticides before there can be any field testing allowed.

Mr. Valentine. Going back to a line of questions that Mr. Volkmer got into before this last break, on the question of equitable relief, and preliminary injunction, temporary restraining order and that kind of thing, has the agency ever attempted that, have you ever gone to a judge and received a temporary restraining order or any other type of preliminary injunctive relief?

Ms. Hollander. Are you asking about under TSCA?

Mr. Valentine. Yes.

Ms. HOLLANDER. I am not aware of any, and I am not sure but I think the answer is no, that we have not.

Mr. VALENTINE. Well, has there been a situation where that was given serious consideration?

What I am really trying to get at is has it been thus far a situation where you really feel that you have been able to intervene and stop this type of activity by the threat of the long arm of the Government, or court action?

Ms. HOLLANDER. The answer to your first question is I don't know how serious it has been considered before, I would have to ask people who have possibly been involved in that. I think the important point is that we think that it is available to us, and that with the case of living micro-organisms we feel that our authority can be used effectively, and may be an important authority for us to use, if the need ever arises.

Mr. VALENTINE. This type of technology we are dealing with something that is in a class by itself. This sort of thing is even a way worse than the Russian's Chernobyl, isn't it; you have got organisms that if released into the environment can just multiply and multiply and it can just turn out to be something that we just don't have any control over.

Mr. SCHATZOW. No, I don't think I would agree with that at all, actually. I think the facts are that there are first of all, within the range of microbial organisms there are many natural microbial organisms which replicate in the environment. Many of the genetically engineered organisms are very parallel and similar to those natural organisms. And many of those natural organisms, we have been dealing with for years. I think someone testified earlier, I heard, that there are approximately 14 different active ingredient pesticides that are registered as microbial biorationale pesticides they are viewed generally as preferable in many cases to traditional chemicals, because they do not have the kind of inherent toxicity, and in many cases do not have the persistence, that we run into with chemicals.

So to suggest that genetically engineered micro-organisms as a class present some significantly different risk than the ones we have been dealing with historically, I think is just wrong.

Mr. VALENTINE. Do either one of you know a gentleman by the name of Jeremy Rifkin?

Mr. SCHATZOW. I have spoken to Mr. Rifkin on the phone a number of times.

Mr. VALENTINE. Yesterday he testified that EPA has abandoned its research efforts to develop a predictive ecology; is that the case?

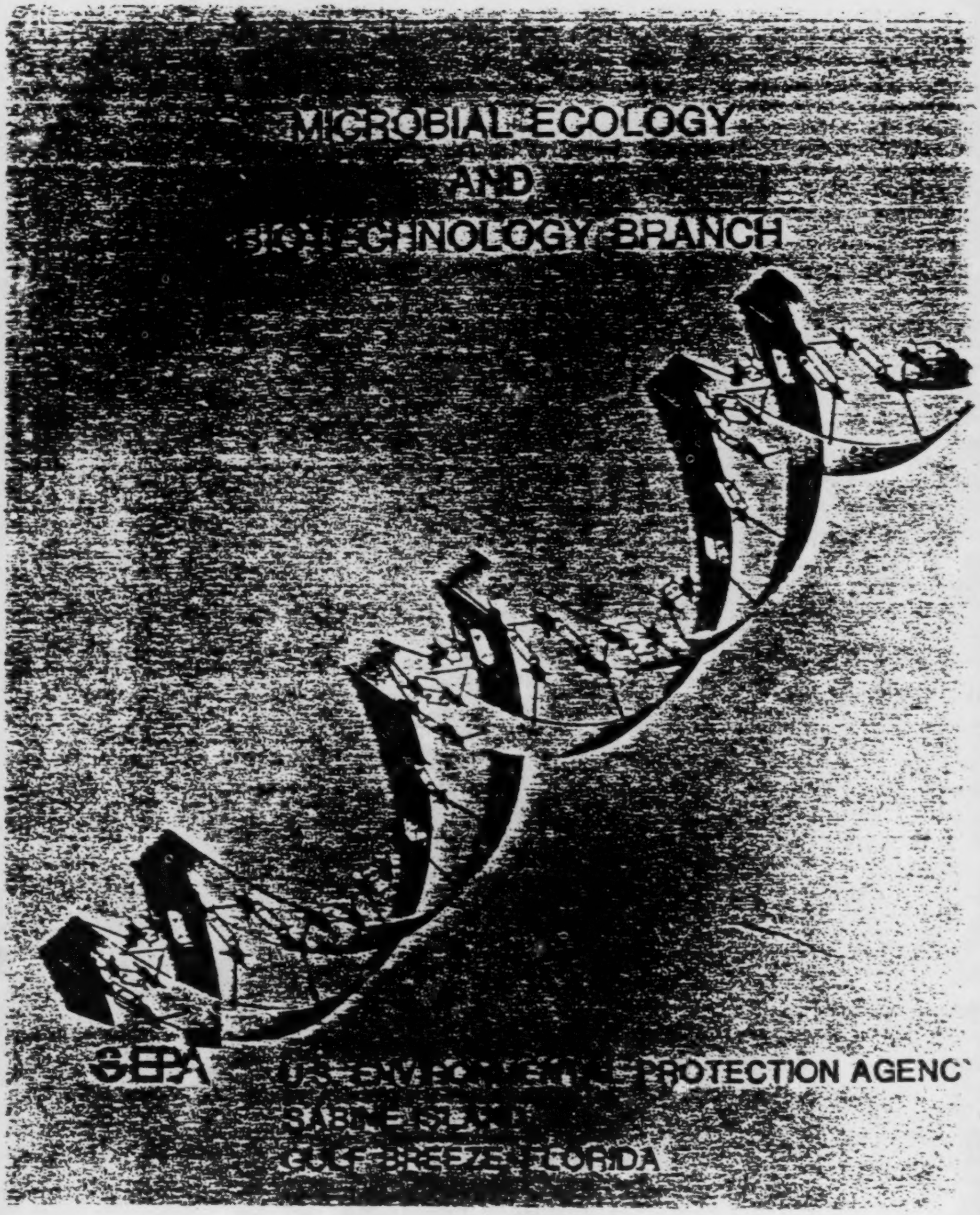
Mr. SCHATZOW. No, that is not the case. The area of predictive ecology, or environmental risk assessment, is one that the agency has been putting more and more money into, both specifically as it relates to the genetically engineered micro-organisms—and we have got major research programs underway, both at EPA's Corvallis Lab, and Gulf Breeze Lab, in that area—as well as outside the area of genetically engineered micro-organisms in dealing with a variety of questions in terms of chemical assessment as it relates to ecological risk as opposed to human health risk.

In fact, under the Pesticides Act, some of the most recent actions we have taken for chemicals like carbofuran, and diazinon, and tributyl tins have been based upon these kind of ecological concerns rather than human health concerns.

Mr. VALENTINE. We request that you, for the record, supply us a description of EPA's present research activities for assessing the risks of environmental releases including a description of both inhouse and extramural programs, with the budget figures for both fiscal year 1986 and 1987, if you would?

Mr. SCHATZOW. We would be happy to do that, Mr. Chairman.

[The information follows:]



MICROBIAL ECOLOGY
AND
BIOTECHNOLOGY BRANCH

EPA U.S. ENVIRONMENTAL PROTECTION AGENC
SABINE ISLAND
GULF BREEZE, FLORIDA

INTRODUCTION

The Microbial Ecology and Biotechnology Branch at the U.S. Environmental Protection Agency's Environmental Research Laboratory in Gulf Breeze, Florida, conducts research concerning interactions of microorganisms with ecological processes and environmental pollutants to develop a comprehensive knowledge of biochemical/ physiological and genetic mechanisms involved in biodegradation of pollutants in complex ecosystems. A nationally recruited scientific staff with training in molecular biology, microbial ecology, microbial genetics, plasmid ecology, microbial biochemistry and enviromental chemistry has been assembled. The Branch's research interests are focused on the application of molecular genetics to ecological processes and on mechanisms of biodegradation of aromatic and chlorinated hydrocarbons.

The research program is designed to respond to Agency research needs through practical application of innovative independent investigations to complex problems. The Branch has a highly specialized group of scientists who work closely with distinguished visiting scientists from academia, postdoctoral trainees, graduate students, and contract scientists (Technology Applications, Inc.).

MISSION

The Microbial Ecology and Biotechnology Branch is responsible for a research program that describes: 1) microbiological interactions with pollutants, including biodegradation mechanisms and predictive techniques for biodegradation rates, sorption, transport, and products; and 2) the potential risk associated with the application of genetically engineered microorganisms (biotechnology) to the environment. The research develops information on biochemical and genetic mechanisms that control biodegradation of hydrocarbons and pesticides in the environment, including aquatic ecosystems and hazardous waste sites.

Research is conducted to determine how microbial communities interact to degrade toxic organic chemicals. Laboratory systems containing sediment, water, and indigenous microorganisms are used to assess the potential and rate of biodegradation in various ecosystems. These systems attempt to simulate delicate interactions of microorganisms associated with surfaces. Fate of chemicals in laboratory systems is compared with fate in natural systems to assess the validity of laboratory data. Microbial ecology, physiology, biochemistry and genetics techniques are employed, emphasizing the biochemical and genetic mechanisms of aromatic and chlorinated hydrocarbon catabolism.

Researchers also develop methods and data to assess the ecological risk of biotechnology. Their research applies techniques of molecular genetics to ecological studies to address questions on survival and growth of novel microorganisms, including specific ecosystem niche requirements, selective advantages of new genotypes, and potential for causing harmful effects to species, ecosystems, or processes. The work includes techniques to enumerate and detect specific microbes or genetic material in complex ecosystems. Research addresses genetic stability of altered microorganisms, including transmissibility of plasmids and other genetic information in the environment and an assessment of the most logical spectrum of species, plasmids, and environments conducive to gene transfer and acquisition. Emphasis is on the genetic control and regulation of aromatic and chlorinated hydrocarbon catabolism.

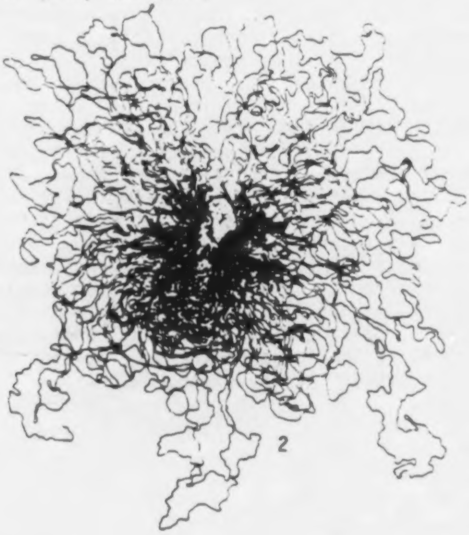
FACILITIES

The Environmental Research Laboratory is located on an island in Santa Rosa Sound near Gulf Breeze and Pensacola, Florida. The Microbial Ecology and Biotechnology Branch conducts research in the Radiochemistry Laboratory (1000 sq. ft.) and in the recently completed Environmental Microbiology Laboratory (4000 sq. ft.). The latest instrumentation is available for research in biochemistry, microbiology, and molecular genetics. The microbiology laboratory is equipped with two automatic autoclaves, a large sterilizing oven, a de-ionizing organic-filter (DI) water system, a reagent-grade water system, a glassware cleaning machine with DI water-rinsing capacity, sinks, benches, etc. A cold room, inoculation room, photographic darkroom, temperature/humidity-controlled environmental chamber, and glassware cleanup/media preparation room are included. The latest in analytical equipment is available for molecular biology studies, including two high speed refrigerated centrifuges (RC-5B, RC-2), an ultracentrifuge (Beckmann LB-50), a Gilson oxygraph, an O-I Corp. carbon analyzer, temperature-controlled incubators, shakers, etc., a Laminar-flow transfer hood, pH meters with thermosensor probes, one Reichert microscope (photomicroscope, standard bright-field phase a contrast research), an automatic pipetting machine, several electrophoresis power supplies and ancillary equipment, and a UV transilluminator table and general and analytical balances.

The radiochemistry laboratory equipment includes six Hewlett-Packard gas chromatographs (two capillary, FID, FPD, EC, TCD) connected to an HP-3357 Laboratory Data System, two Waters high pressure liquid chromatographs (HPLC), a Technicon Auto-analyzer (nitrogen and phosphorus), a Packard sample oxidizer, Omni sample mixers (8), two Beckman liquid Scintillation counters (Model LS-8100, tied to PDP-11/70 computer, and Model LS-250) and four chemical transfer hoods.

Computer facilities include the HP3357, a PDP-11/70, and IBM-PC's. A modern Marine Toxicology Laboratory (10,000 sq. ft.) is equipped with all ancillary equipment for constant salinity, temperature, etc., in flowing sea-water for microcosm or other studies.

For information on the research programs, call the Branch Chief (904) 932-5311 or (FTS) 686-9011.



RESEARCH STAFF

DR. TAMAR BARKAY, Research Microbiologist, received her M.S. in Environmental Health from the Hebrew University in 1976, and her Ph.D. from the University of Maryland in 1980. Dr. Barkay did her postdoctoral work at the Weizman Institute from 1981 to 1982. Her research interests are in the molecular mechanisms of bacterial adaptation to environmental stress by using plasmid mediated mercurial resistance as a model system. She investigates how horizontal gene transfer and other genetic change mechanisms affect the dynamics of microbial communities under environmental stress.

Barkay, T., S. Tripp, and B.H. Olson. 1985. The Effects of Metal Rich Sewage Sludge Application on the Bacterial Communities of grasslands. Appl. Environ. Microbiol. 49:333-337.

Barkay, T., D.L. Fouts, and B.H. Olson. 1985. Preparation of a DNA Gene Probe for Detection of Mercury Resistance Genes in Gram-Negative Bacterial Communities. Appl. Environ. Microbiol. 49:686-692.

DR. AL W. BOURQUIN, Supervisory Research Microbiologist, received his M.S. in Microbial Genetics and his Ph.D. in Microbiology (Biophysics) from the University of Houston in 1968 and 1971, respectively. His research interests are in the mechanisms of natural microbial community interactions to degrade aromatic hydrocarbons in the environment. He uses laboratory ecosystems and biochemical techniques to determine catabolic pathways of aromatic hydrocarbons.

Bourquin, A.W. 1984. Biodegradation in the Estuarine-Marine Environments and the Genetically Altered Microbe. In: Genetic Control of Environmental Pollutants, S. Omenn and A. Hollaender, (eds). Basic Life Sciences, Vol. 28, pages 97-115. Plenum Press, New York, N.Y.

Bourquin, A.W., P.H. Pritchard, W.W. Walker, and R. Parrish. 1984. Biodegradation Kinetics Workshop: Navarre Beach, Florida, 18-20 October 1983. U.S. Environmental Protection Agency, EPA-600/X-84-161, Gulf Breeze, FL. pp. 161.

DR. DEB K. CHATTERJEE, National Research Council Fellow, received his B.S. and M.S. from the University of Calcutta in 1972 and 1974, respectively. He received his Ph.D. in 1981 from the University of Calcutta on research involving isolation, purification and characterization of enzymes. He did his postdoctoral research at the University of Illinois, College of Medicine, in the field of genetic manipulation for the development of bacterial strains capable of degrading toxic aromatic hydrocarbons and the regulation of gene expression. His interests include the stability of microorganisms carrying novel genes in the environment, genetic transfer in natural environments and development of new bacterial strains with novel properties using recombinant DNA technologies.

D.K. Chatterjee and A.M. Chakrabarty. 1984 . Restriction Mapping of Chlorobenzoate Degradative Plasmid and Molecular Cloning of Degradative Genes. Gene 27, 173-181.

D. Ghosal, I.S. You, D.K. Chatterjee and A.M. Chakrabarty. 1985. Microbial Degradation of Halogenated Compounds. Science *228*, 135-142.

DR. PETER J. CHAPMAN, EPA-Distinguished Visiting Scientist (1985-87), is a Professor of Microbiology and Biochemistry with the University of Minnesota, St. Paul. He received his Ph.D. in 1961 from the University of Leeds. He was the recipient of a Fullbright Scholarship and has authored or co-authored over 70 scientific publications on microbial degradation of alicylic and aromatic compounds. Dr. Chapman's research interests include the study of the biochemical mechanisms of biodegradation of chlorinated compounds and understanding the molecular basis of biodegradation mechanisms. He is currently investigating cometabolism processes in work that bridges microbial ecology and microbial physiology, using multi-substrate systems under controlled conditions.

Hagedorn, S.R., Bradley, G., and Chapman, P.J. 1985. Glutathione-Independent Isomerization of Maleyl-pyruvate by *Bacillus Megaterium* and Other Gram-Positive Bacteria. J. Bacterial. *163:640-647.*

Liu, Ting and P.J. Chapman. 1984. Purification and Properties of a Plasmidencoded 2,4-Dichlorophenol Hydroxylase. FEMS *Letters* *173*:314-318.

DR. ANANDA CHAKRABARTY, EPA-Distinguished Visiting Scientist (1985-88), is a Professor of Microbiology from the University of Illinois, College of Medicine. He received his Ph.D. in 1965 from the University of Calcutta. He has numerous patents and was selected the Industrial Research Scientist of the Year (1975) and the CPLA Inventor of the Year (1982). He is author or co-author of over 90 publications on the molecular basis for genetic expression and regulation. His research interests include the role of *Pseudomonas* in cystic fibrosis infections, the genetic manipulation of bacteria and their plasmids to degrade synthetic toxic chemicals, and hydrocarbon microbiology and oil recovery.

Chakrabarty, A.M. 1985. Genetic Engineering and Problems of Environmental Pollution. In *Biotechnology*, Vol. 8. H.J. Rehm and G. Reed, eds., Verlag Chemie, Weinheim.

Frantz, B. and A. Chakrabarty. 1985. Degradative Plasmids in *Pseudomonas*. In: *The Bacteria*, Vol. 10. J.R. Sokatch and L.N. Ornston, eds., Academic Press, NY.

DR. STEPHEN M. CUSKEY, Research Microbiologist, received his B.S. in Biology from the Bucknell University in 1975 and his Ph.D. in Microbiology from Cook College, Rutgers University in 1982. Dr. Cuskey did his postdoctoral work at Virginia Commonwealth University (1982-84) on the genetic control of carbohydrate catabolism by *Pseudomonas aeruginosa* and at the University of Michigan (1984-85) on the molecular cloning and characterization of genes controlling aromatic hydrocarbon catabolism of aromatic compounds by *Pseudomonas aeruginosa* and *Streptomyces* sp. His research interests include the charactzation, cloning, and expression of genes involved in aromatic degradation and the mobility of novel genes in natural ecosystems. He investigates the effects of conditionally lethal traits on the survival and expression of genetic traits in the environment.

Cuskey, S.M. and P.V. Phibbs, Jr. 1984. Chromosomal Mapping of Mutations Affecting Glycerol and Glucose Catabolism in Pseudomonas aeruginosa PAO. J. Bacteriol. 162:872-880.

Cuskey, S.M., J.A. Wolff, P.V. Phibbs Jr., and R.H. Olsen. 1984. Molecular Cloning of Genes Specifying Carbohydrate Catabolism in Pseudomonas aeruginosa and Pseudomonas putida. J. Bacteriol. 162:865-871.

DR. FRED GENTHNER, Research Microbiologist, received his B.S. in Biology from Carthage College in 1974, his M.S. in Microbiology from Southern Illinois University in 1977, and his Ph.D. from the University of Illinois in 1983. Dr. Genthner's postdoctoral work at the University of Missouri (1983-84) concerned a genetic and regulatory analysis of nitrogen fixation in the photosynthetic bacterium Rhodopseudomonas capsulata. He has developed a rapid HPLC method to measure genome size and estimate plasmid copy number for use in conjunction with high density bacterial fermentations. Dr. Genthner is interested in genetic exchange and recombination, nitrogen fixation, and plasmid stability, especially as related to evolutionary consequences within microbial communities.

Genthner, F.J. and J.D. Wall. 1984. Isolation of a Recombination Deficient Mutant of Rhodopseudomonas capsulata. J. Bacteriol. 160:971-975.

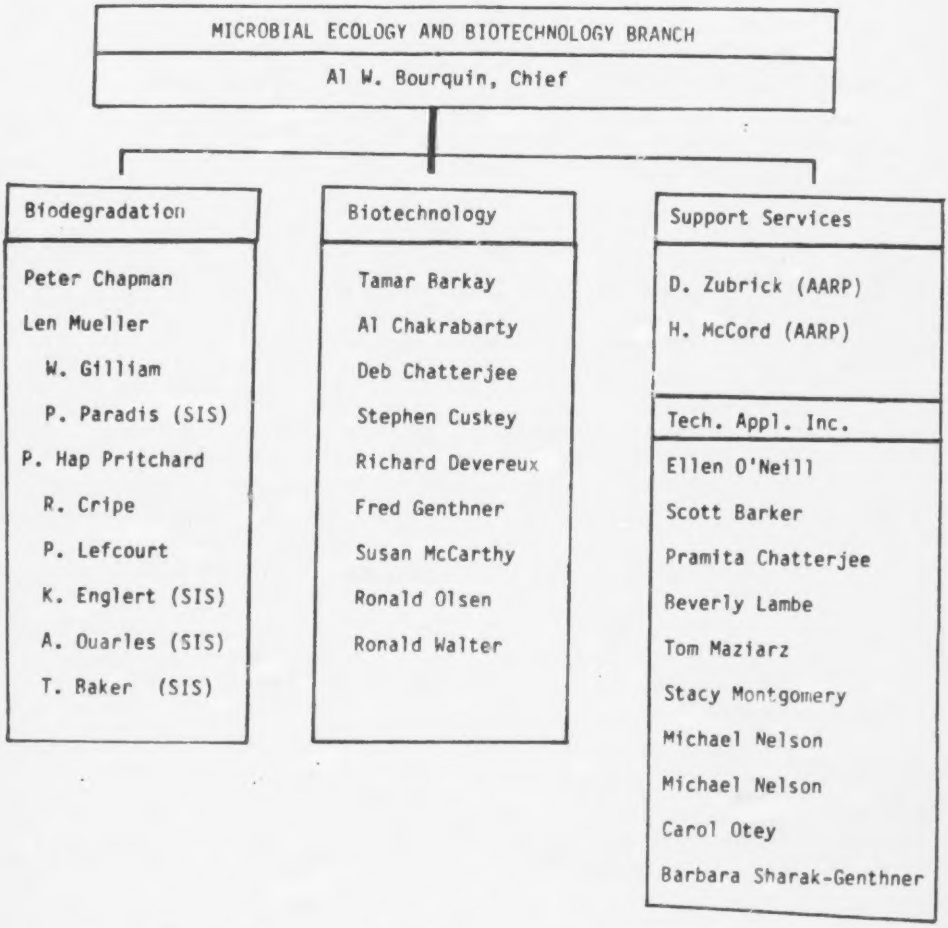
Genthner, F.J., L.A. Hook, and W.R. Strohl. 1985. Determination of the Molecular Mass of Bacterial Genomic DNA and Plasmid Copy Number by High Performance Liquid Chromatography. Appl. Environ. Microbiol. 50:1007-1013.

MR. LEN MUELLER, Research Chemist, received his B.A. in Chemistry from the Mankato State University in 1964. Mr. Mueller is the chief analytical chemist for hydrocarbon and pesticide residue analyses in water, sediment, and biota. His interests include metabolite isolation, quantitation and low level analyses of toxic substances such as PCB's.

O'Neill E.J., C.R. Cripe, L.H. Mueller and P.H. Pritchard. Fate of Fenthion in Salt Marsh Environments: Transport and Biodegradation in Microcosms. (In Preparation).

Mueller, L.H., W. Gilliam, A.W. Bourquin, and P.H. Pritchard. Fate of Fenthion in Salt Marsh Environments: Results from a Field Application (Abstract). Society of Environmetal Toxicology and Chemistry (SETAC), Nov. 4-7, 1984. Arlington, VA. p. 299.

DR. RONALD H. OLSEN, EPA-Distinguished Visiting Scientist (1985-88), is a Professor of Microbiology at the University of Michigan Medical School. He received his Ph.D in 1962 from the University of Minnesota. He has consulted with numerous industries including developing biotechnology programs; he possesses 18 patents in and outside the U.S. He has authored or co-authored over



MICROBIAL ECOLOGY AND BIOTECHNOLOGY BRANCH

Al W. Bourquin, Chief

Biodegradation

- Peter Chapman
- Len Mueller
  - W. Gilliam
  - P. Paradis (SIS)
- P. Hap Pritchard
  - R. Cripe
  - P. Lefcourt
  - K. Englert (SIS)
  - A. Ouarles (SIS)
  - T. Baker (SIS)

Biotechnology

- Tamar Barkay
- Al Chakrabarty
- Deb Chatterjee
- Stephen Cuskey
- Richard Devereux
- Fred Genthner
- Susan McCarthy
- Ronald Olsen
- Ronald Walter

Support Services

- D. Zubrick (AARP)
- H. McCord (AARP)

Tech. Appl. Inc.

- Ellen O'Neill
- Scott Barker
- Pramita Chatterjee
- Beverly Lambe
- Tom Maziarz
- Stacy Montgomery
- Michael Nelson
- Michael Nelson
- Carol Otey
- Barbara Sharak-Genthner

50 scientific publications on microbial genetics. Dr. Olsen's research interests include utilizing cloning vectors for Pseudomonas to study the manner in which transferable resistance to antibiotics occurs among bacteria, and for the derivation of gene banks from Streptomyces or Phanerochaete for the biodegradation of lignin. Other interests include the biochemical genetics and plasmid biology of Pseudomonas on the biodegradation of environmental pollutants.

Gonzala, C.F., S. Layher, A.K. Vidover, and R. H. Olsen. 1984. Molecular Cloning in Pseudomonas syringae pv. syringe an Assessment of the Contribution to Virulence by Indigenous Plasmid p CG131. Phytopathol. 74:1245.

Olsen, R.H. 1984. Utilizing Microorganisms to Delignify Wood. In: International Symposium of Recent Advance in Forest Biotechnology. Traverse City, MI, Michigan Biotechnology Institute.

DR. PARMELY H. PRITCHARD, Research Microbiologist, received his M.S. in Microbiology in 1966 and his Ph.D. in 1969 from Cornell University. Dr. Pritchard did postdoctoral work at the Woods Hole Oceanographic Institution, from 1969 to 1971. His primary research interests are the interactions of aquatic microbial communities in the degradation of toxic organic chemicals, the assessment of the validity of laboratory data in microcosms for predicting exposure concentrations in aquatic ecosystems.

Pritchard, P.H. and A.W. Bourquin. 1984. The Use of Microcosms for Evaluation of Interactions between Pollutants and Micoorganisms. Adv. Microbial Ecol. 7:133-215.

O'Neill, E.J., C.A. Monti, P.H. Pritchard, A.W. Bourquin, and D.G. Ahearn. 1985. Effects of Lugworms and Seagrass on Kepone (Chlordecone) Distribution in Sediment-Water Laboratory Systems. Environ. Toxicol. Chem. (4) 4:453-458.

DR. RONALD B. WALTER, National Research Council Fellow, received his B.S. and M.S from the Florida State University in 1979 and 1981, respectively. He received his Ph.D. in 1985 from the Florida State University on research involving genetic transformation, genetic recombination and DNA repair mechanisms in Haemophilus influenzae. His current research interests involve the investigation of gene transfer in artificial microcosms using Bacillus sp. as a model system.

Stuy, J.H. and R.B. Walter. 1985. Facilitated Plasmid Transfer in Haemophilus influenze: Influence of Homology between the Plasmid and Chromosome. Mol. Gen. Genet. (In Press).

Stuy, J.H., and R.B. Walter. 1981. Addition, Deletion, and Subsitution of Long Nonhomologous Deoxyribonucleic Acid segments by Genetic Transformation of Haemophilus influenze. J. Bacteriol. 148:565-571

TECHNOLOGY APPLICATIONS, INC.

Research Staff

THOMAS MAZIARZ, Chemist, received his B.S. in Biology from the University of West Florida in 1977. His research interests include the fate of organic chemicals including chlorinated phenols, pyrethroid pesticides and aromatic and polyaromatic hydrocarbons in water, sediment and benthic organisms from estuarine environments.

> Pritchard, P.H., A.W. Bourquin, H.L. Fredrickson and T.P. Maziarz. 1978. System Design Factors Affecting Fate Studies in Microcosms. In: Proceedings of the Workshop: Microbial Degradation of Pollutants in the Marine Environment. pp. 251-272.
>
> Pritchard, P.H., J.C. Connally, M.E. Cleveland, T.P. Maziarz, and A.W. Bourquin. 1980. Modeling the Fate of Pesticides in Estuarine Sediment - Water Microcosms. Presented at the National American Society of Microbiologists (ASM), Miami, 1980.

DR. MICHAEL NELSON, Research Microbiologist, received his B.S. in Zoology from Texas A&M University in 1975, and his Ph.D. in Microbiology from the University of Texas at Austin in 1982. Dr. Nelson did his postdoctoral work at the Virginia Polytechnic Institute and State University involving the physiology and biochemistry of methanogenic microorganisms. His research interests include determining the microbiology and biochemistry involved in the degradation of xenobiotic compounds with a particlular interest in dehalogenation of halo-organic compounds and applying techniques of molecular genetics to enhance microbial abilities for biodegradation.

> Sowers, K.R., M.J. Nelson, and J.G. Ferry. 1985. Growth of Acetotrophic, Methane-Producing Bacteria in a pH Auxostat. Curr. Microbiol. 11:227-230.
>
> Nelson, Michael J.K., David P. Brown, and James G. Ferry. 1984. FAD Requirement for the Reduction of Coenzyme F_{420} by Hydrogenase from Methanobacterium Formicisum. Biochem. Biophysic. Res. Comm. 120(3):775-781.

Ms. ELLEN O'NEILL, Research Microbiologist, received her B.S. and M.S. in Biology from the University of West Florida in 1977 and 1981, respectively. Her research interests include the fate of organic pollutants in estuarine sediment/water microcosms and field situations with application of mathemathical models to experimental data.

> O'Neill, E.J., C.A. Monti, P.H. Pritchard, A.W. Bourquin, and D.G. Ahearn. 1985. Effects of Lugworms and Seagrass on Kepone (Chlordecone) Distribution in Sediment-Water Laboratory Systems. Environ. Toxicol. Chem. (4) 4:453-458.

P.H. Pritchard, Monti, C.A., E.J. O'Neill, A.W. Bourquin, and D.G. Ahearn. Modeling the Movement of Kepone (Chlordecone) Across an Undisturbed SedimentWater Interface in Laboratory Systems. Environ. Toxicol. Chem. (In Press).

DR. BARBARA SHARAK-GENTHNER, received her M.S. in Microbiology from Southern Illinois University in 1978, and her Ph.D. from the University of Illinois in 1984. Dr. Sharak-Genthner did her postdoctoral work at the University of Missouri investigating ammonium transport in Rhodopseudomonas capsulata, and anaerobic degradation of halogenated compounds at Battelle Memorial Research Institute. Her main area of interest is the isolation and characterization of new anaerobic species of bacteria whose biological processes can be harnessed for useful purposes. At present, she is continuing to investigate anaerobic degradation of toxic compounds.

R.L. Gregory, B.R. Sharak-Genthner, and I.L. Shechmeister. 1983. Absence of Plasmid-Like Material in a Glucosyltransferase-Defective Noncariogenic Mutant of Streptococcus Mutans. IRCS Med. Sci. 11:561-562.

Sharak-Genthner, B.R. and J.D. Wall. 1985. Glutamine Synthetase Activity and Ammonium Transport in Rhodopseudomonas Capsulata. Archives of Microbiology (In Press).

06/06/86

BIOTECHNOLOGY

		FY-85	FY-86*	FY-87
OEPER	L104 - H - 24	$ 1241.5	3430.4	3895.8
		FTE 6.4	7.4	7.4
OHR	L104 - H - 21	101.3	292.1	168.9
		1.0	1.4	1.4
	L104 - H - 22	101.3	242.1	168.9
		1.0	1.4	1.4
OEET	L104 - H - 23	29.9	539.9	531.5
		0.5	1.5	1.5
SUBTOTAL -	L104 (TSCA)	1474.0	4505.5	4765.1
		8.9	11.7	11.7
OEPER	E104 - H - 11	—	--	1621.2
				13.8
OHR	E104 - H - 12	--	—	868.0
				4.2
SUBTOTAL -	E104 (FIFRA)			2489.2
				18.0
TOTAL - BIOTECH+		1474.0	4504.5	7254.3
		8.9	11.7	29.8

*FY-86 RESOURCES ARE AS OF 04/01/86 ALLOWANCES

CLUDES PROJECTS PREVIOUSLY IDENTIFIED AS "BIORATIONAL PESTICIDES"

MICROBIAL ECOLOGY AT CERL

Overall Mission

The Microbial Ecology/Biotechnology Team is responsible for developing test methods based on research and databases concerning the potential risks of microbial pest control agents and genetically-engineered microorganisms on terrestrial ecosystems and effects of hazardous pollutants on microbial processes, activities, and interactions with other living components.

The activities include:

A. The development of methodologies to assess environmental risks from genetically-engineered microorganisms (OTS,OPP).

B. The development of scientific protocols for testing the effect of biological control agents to non-target organisms (OPP).

C. The development of environmental risk models to estimate and predict the impact of xenobiotic chemicals to microbial populations involved in nutrient transformations important to plants (OTS, OPP).

MICROBIAL ECOLOGY/BIOTECHNOLOGY

Laboratory Physical Components

1. Main Laboratory
    - a. Three P2 biotechnology laboratories
    - b. Soils microbiology/microbial ecology laboratory.
    - c. Enzymology/analytical biochemistry laboratory
    - d. Virus laboratory for biological control agent research.
    - e. Insectory
2. Microcosm Containment facility
3. Avian Test facility
4. Greenhouse/plant toxicology laboratory
5. Soils preparation laboratory
6. Tissue culture containment facility

Recent Accomplishments of the Program

I. Biotechnology

Aided in the preparation of the report:

1. Aided in the preparation of the report: Research Needs in Biotechnology the and Environment, 1985, Office of Public Sector Programs, American Association for the Advancement of Science, Washington, DC

2. Gave presentations on EPA's coordinated biotechnology plan for Congress, OPTS and ORD.

3. Evaluated four methods of measuring DNA transfer between candidate GEMs for use in the terrestrial environment.

4. Demonstrated applicability of "simple" and "complex" microcosms for simulating environmental conditions for detecting and measuring DNA transfer events.

5. Invited to Fourth International Conference on Safety Evaluation and Regulation; Safety Evaluation in Biotechnology.

6. Establishment of FY 85 extramural program to support the first projects dealing directly with established agency risk assessment needs in terrestrial biotechnology (Michigan State; New York University).

7. Sponsored summer workshop to develop program plans for FY 86 extramural biotechnology research program in both terrestrial and aquatic areas.

II. Biological Control Agents

1. Developed interim protocols for biological control agents

   a. Predatory mites--reviews completed
   b. Predatory Chrysopidae (lacewing) -- in review
   c. Predatory Lygaeidae--in review
   d. Predatory Hymenopterans--in preparation
   e. Predatory Coleoptera--in preparation

2. Developed quantitative MPCA inoculation/artifical diets to culture nontarget beneficial arthropods.

3. Completed construction of working instrumentation for Electronic Bioassay System to evaluate effects of MPCA's on insects.

4. Completed initial steps for a computer searchable data base on effect of biological agents on arthropods.

5. Published manuscript entitled "Effects of MPCAs on Non-Target Beneficial Arthropods" by Flexner, Lighthart and Croft; in press: Agriculture, Ecosystems, and Environment

6. Completed interim protocols on oral and intraveneous exposure of avian species to MPCAs. Protocol on inhalation is under development.

7. Established tissue culture facility for propagating baculoviruses.

III. Microbial Ecology

1. Developed new research laboratory for studying the effect of chemicals on microbial initiated processes and biodegradation.

2. Recruiting technical help for establishing research in studying microbial mediated transformations in soil.

INHOUSE RESEARCH
IN MICROBIAL ECOLOGY/BIOTECHNOLOGY

PROJECT TITLE: Fate and genetic stability of genetically-engineered microorganisms in the terrestrial environment.

PRINCIPAL INVESTIGATORS: Ramon Seidler, Mike Walter and Arlene Porteous

INSTITUTION: Corvallis Environmental Research Laboratory

OBJECTIVES: To develop test methods for studying the genetic stability of GEMs, particularly those impacting terrestrial environments. In the development of these test methods, a combination of laboratory as well as simple and complex microcosms approaches are envisioned.

Further objectives include determining applicability of laboratory techniques in quantitatively detecting transconjugants which may form in microcosms, and ascertaining whether indigenous recombinants which received engineered DNA can in turn become donors of this engineered DNA to indigenous species. Further subobjectives include determining whether a generalized technique can be developed to detect transfer of DNA from GEM species into certain components of the natural flora. The stability of engineered DNA within a GEM is influenced by a complex array of factors, both biological as well as physical/chemical. A longer term objective is to address the effects of GEM DNA stability on control of substrate utilization specificity and gene expression within transconjugants.

OUTPUTS: Special Report: Conjugal DNA transfer among bacteria: techniques, issues, and findings relevant to the release of GEMs.

Special Report: A data base for detecting, identifying, and enumerating GEMs released into terrestrial environments.

Journal Article: An evaluation of four techniques for the detection and enumeration of transconjugants in laboratory media.

PROJECT TITLE: Survival and fate of genetically-engineered microorganisms in the insect-plant ecosystem.

PRINCIPAL INVESTIGATORS: John Armstrong, Guy Knudsen

INSTITUTION: Corvallis Environmental Research Laboratory

OBJECTIVES: The primary objective of this research is to study the survival, fate, and genetic stability of engineered microbes (GEMs) in insects feeding on plants that have been sprayed with GEMs. The objective includes the development of test methods to evaluate factors important in the survival and fate of specific groups of GEM species appropriate to those that industry is developing for release into the plant/terrestrial ecosystem. Understanding the role of the insect gut and how that ecosystem affects the survival, genetic stability and fate of GEMs are significant subobjectives. The role of the plant system and the physical/chemical environs (daylight hrs, humidity, temperature) are fundamental parameters which can impact GEM survival and thus genetic stability.

OUTPUTS: Journal Article: Fate and survival of recombinant bacteria and recombinant DNA in insects.

Journal Article: Regrowth of recombinant bacteria and persistence of DNA in insect frass.

Test methods for studying the fate and genetic stability of GEMs in the insect/plant ecosystem.

PROJECT TITLE: Microbial Ecology/Risk Assessment

PRINCIPAL INVESTIGATOR: Charles Hendricks

OBJECTIVE: Prepare necessary planning documentation to develop a terrestrial microbial ecology program on risk assessment. This is to include appropriate material on the in situ treatment of hazardous wastes.

INSTITUTION: Corvallis Environmental Research Laboratory

ACCOMPLISHMENTS: Toward the goal of establishing a new laboratory in terrestrial microbial ecology, the following has been accomplished.

1. Completed nine month sabbatical leave at the Department of Plant & Soil Biology, University of California, Berkeley
2. Completed transfer to CERL
3. Draft manuscript - Growth

Measurements of Terrestrial Microbial

Species by a Continuous-Flow Technique

PROJECT TITLE: Effects of Microbial Pesticides on Non-Target, Beneficial Arthropods

PRINCIPAL INVESTIGATORS: Bruce Lighthart and Brian Croft

INSTITUTION: CERL, OSU

OBJECTIVES: To develop tests to evaluate the effects of microbial pest control agents (MPCA) on beneficial arthropods taken from five insect and mite orders.

To use the above information in conjunction with a literature data base and expert information in a decision support system to help decide the risk(s) inherent in the use of potential MPCAs.

OUTPUTS:

1. Optimized protocols for each of five tested insects.

2. Journal Articles: Effects of stress conditions on the infectious processes of entomopathogenic viruses, bacteria, fungi and protozoa.

3. Software: A user friendly microcomputer program to assist personnel in evaluating the risk(s) involved with the use of a potential MPCA.

PROJECT TITLE: Development and Validation of Protocols for Safety of Microbial Pest Control Agents to Avian Species

PRINCIPAL INVESTIGATORS: M. D. Knittel and A. Fairbrother

INSTITUTION: Corvallis Environmental Research Laboratory

OBJECTIVES: The project has two objectives: (1) Development and validation of interim protocols for the intravenous, oral and respiratory inoculation of test avian species with MPCA; and (2) the development of In Vitro test protocols to determine safety of MPCA to avian species.

OUTPUTS:

1. Interim protocol for the oral evaluation of safety of MPCAs to avian species.
2. Iterim protocol for the intravenous evaluation of safety of MPCAs to avian species.
3. Interim protocol for the respiratory evaluation of safety of MPCAs to avian species. Draft ready for review.
4. Journal article on In Vitro testing of MPCAs.

EXTRAMURAL RESEARCH

TITLE: Fate and effects of genetically-engineered microbes in terrestrial environments

PRINCIPAL INVESTIGATORS: Guenther Stotzky

INSTITUTION: New York University

STATE DATE: June 1985 RESOURCES: $228,000

OBJECTIVES: The objectives are to develop test methods and protocols for evaluating the fate, survival, and genetic stability of GEMs released to terrestrial ecosystems. The overall objectives are being achieved through analyses of growth and survival of many species of GEMs released into many soil types collected from around the world. Broth sterile and natural soils are used. Genetic stability involving the transfer of naked DNA molecules released from GEMs as well as the role of bacterial viruses in the genetic transfer processes will also be evaluated.

OUTPUTS:

Journal article on the survival and genetic transfer by GEMs in natural terrestrial environments.

Journal article on the fate in soil of a recombinant plasmid carrying a Drosophila gene.

Journal article on the transformation and transduction processes in soils which influence the genetic stability of GEMs.

TITLE: Methods for assessing fate of genetically engineered microorganisms in soil

PRINCIPAL INVESTIGATORS: James Tiedje and Barry Chelm

INSTITUTION: Michigan State University

AWARD DATE: July 85 RESOURCES: $135,000

OBJECTIVE: The primary objective is to establish and verify test methods which would describe the fate and survival of GEMs in soil ecosystems. The subobjectives involve the development of a method for the quantitative recovery of GEMs from soil followed by an enmasse extraction of DNA and probing specific sequences; develop a soil microcosm that minmics the natural environment in order to soil parameters which influence survival of GEMs.

OUTPUTS:

Journal article on a method for the recovery of GEMs from soil for DNA probe analyses of genetically-engineered DNA sequences.

Journal article on the use of a soil column technique for evaluating chemical factors influencing the fate and survival of genetically-engineered microbes in soil.

TITLE: Evaluation of terrestrial microcosms for assessing the fate and effects of genetically engineered microorganisms on ecological processes

PRINCIPAL INVESTIGATOR: Peter Van Voris

INSTITUTION: Battelle Memorial Institute Northwest

AWARD DATE: New Estimated June 1986 RESOURCES: $196,000

OBJECTIVE: To evaluate and modify the existing EPA/OTS terrestrial microcosm test system and test protocol such that they can be used to determine the environmental fate and ecological hazards of genetically engineered organisms. The intact soil-core microcosm design closely represents natural terrestrial ecosystems and when coupled with appropriate test protocols can be used to define and limit risks associated with the deliberate release of GEM's.

OUTPUTS:

Validated protocol of a soil core to test the fate and effects of GEMs on ecological processes.

Journal article on the use of soil cores for studying GEM effects on plants.

Journal article on test methods for studying the effects of GEMs on soil/plant nutrient cycles.

TITLE: Effect of Foreign Genes on Virulence of Pathogenic Fungi

PRINCIPAL INVESTIGATOR: O. C. Yoder

INSTITUTION: Cornell University

AWARD DATE: New Estimate June 1986 RESOURCES: $226,931

OBJECTIVES:

Determine the effect of foreign pathogenicity genes on the virulence, host-specificity, and/or survival of saprophytic and pathogenic filamentous fungi.

Develop a test method to determine exchange of recominant DNA among fungi.

Determine the effect of heterologous "neutral" genes on the virulence of a pathogen carrying this DNA in its genome.

OUTPUTS:

Journal article on the influence of foreign pathogenic genes on the virulence, host-specificity, and survival of saprophytic fungal species.

Journal article on the effects of foreign "neutral" genes on the virulence and physiology of pathogenic fungal species.

TITLE: Effects of released recombinant streptomyces on the microbiolgy and ecological processes of a soil ecosystem

PRINCIPAL INVESTIGATOR: Donald Crawford

INSTITUTION: University of Idaho

AWARD DATE: New Estimated June 1986 RESOURCES: $174,130

OBJECTIVE:

To develop protocols for assessing the effects of gram positive bacteria on ecological processes in the soil.

Determine the effects of genetically altered Streptomyces on native gram positive organisms in the soil.

Determine whether the Strepytomyces recombinants effect major ecological processes with an emphasis on elucidating their long-term effects on the cycling of organic carbon.

OUTPUTS:

Journal article on the persistence and fate of recombinant lignin biodegrading Streptomyces released to terrestrial ecosystems.

Test method for evaluating effects of recombinant lignin biodegraders on the cycling of carbon in terrestrial environments.

TITLE: Effects of genetically-engineered microbes on ecological processes in soil.

PRINCIPAL INVESTIGATOR: Guenther Stotzky

INSTITUTION: New York University

AWARD DATE: New Estimated June 1986 RESOURCES: $270,775

OBJECTIVES: Develop test methods based upon enzymatic, nutritional, physiological, functional, and taxonomic criteria for evaluating the potential effects of GEMs on ecological processes. Determine which, if any, enzymatic assays are sensitive, economical, and convenient for detecting effects from GEMs; develop a series of physiological and nutritional tests for indexing microbial species diversity effects of GEMs; evaluate various broad, functional kinetic activities such as nitrification, respiration, dinitrogen fixation, etc., which may be influenced following the release of GEMs into an ecosystem.

OUTPUTS:

Journal article on the influence of GEMs released into terrestrial ecosystems on enzymatic processes in soil.

Journal article on the microbial species diversity index to detect potential influences of GEMs on terrestrial microflora.

Journal article on series of test to measure the effects of GEMs on key functional processes occurring in soil.

Special report on an index of appropriate measurements for evaluating the effects of GEMs on biochemical and taxonomic features of the terrestrial ecosystem.

TITLE: Impact of energy controlled survival on the stability of plasmid DNA in genetically-engineered microorganisms.

PRINCIPAL INVESTIGATOR: Richard Morita

INSTITUTION: Oregon State University

AWARD DATE: New Estimated June 1986 RESOURCES: $199,917

OBJECTIVES: Determine if energy-controlled survival has an impact on the maintenance of foreign (engineered) DNA, especially plasmid DNA, in prokaryotic cells. Determine whether the loss of plasmid DNA is a generalized phenomenon common to many candidate GEM species and whether this loss of plasmid DNA is related to plasmid in group, size, and metabolic functions encoded; determine how long a GEM must be starved before loss of plasmid; determine the relative relationship between the net available nutritional energy in a given terrestrial enviroment and the loss of the plasmidS; what relative energy level is necessary for the maintenance of plasmid DNA molelcules; is there any relationship between cell deatth and plasmid loss; ascertain whether there are correlations between nutrition and physiological conditions and loss of plasmid DNA.

OUTPUTS:

Journal article on the relationship between the available energy in the terrestrial environment and the persistence of GEMs.

Journal article on the maintenance of recombinant DNA in GEMs as a function of plasmid size, function, and available energy in the ecosystem.

Journal article on the morphological changes during long-term starvation survival and the loss of plasmid DNA.

TITLE: Evaluation of novel methods for detection of recombinant DNA in the soil environment

PRINCIPAL INVESTIGATOR: Betty Olson

INSTITUTION: University of California, Irvine

AWARD DATE: New Estimate June 1986 RESOURCES: $198,775

OJECTIVE: Develop a generalized test method for optimal detection enumeration of GEMs in terrestrial ecosystems. The objective will be acieved through an investigation of the efficacy or riboprobes, nonradioactive probe analysis, direct detection of R-DNA in soil, and a validation of these methods in a terrestrial microcosm.

OUTPUTS:

Journal article comparing conventional DNA probes with riboprobes in the detection of GEMs in terrestrial environments.

Journal article on a novel technique for the direct detection of R-DNA in soil samples.

Journal article on validation of new methods for detecting GEMs in a terrestrial ecosystem.

TITLE: Ice nucleation and bioluminescence as sensitive tools for detection

PRINCIPAL INVESTIGATOR: Trevor Suslow

INSTITUTION: Advanced Genetic Sciences

AWARD DATE: New Estimate June 1986 RESOURCES: $165,393

OBJECTIVE: To determine the feasibility of using the bioluminescent (lux) gene and ice nucleation active gene (INA) as markers to detect genetically engineered microorganisms in terrestrial environments. The system, if successful, will allow us to rapidly, conveniently and sensitively assess the fate of GEMs in the environment.

OUTPUTS:

Method to incorporate the Lux and INA genes into GEMs for the purpose of detection within a controlled environment.

Journal article on the use of lux genes in the detection of GEMs released to plant roots.

Journal article on the fate of Pseudomonas in a terrestrial microcosm as measured by lux genes and INA gene expression.

TITLE: Determination of the fate and effects of released recombinantly generated microorganisms and their parental strains compared with measurements made in contained environments

PRINCIPAL INVESTIGATOR: Steven Lindow

INSTITUTION: University of California, Berkeley

AWARD DATE: New Estimated June 1986 RESOURCES: $196,235

OBJECTIVE:

To determine the fate of introduced microorganisms on treated plants, soil and other habitats following application of such organisms at concentrations used in microcosm studies and used in typical release scenarios in the field.

To determine the effects of variable inoculum concentrations of introduced microorganisms on population size and changes in associate micro and macroflora on plants and in the soil.

To measure spacial flux of microorganisms from sites of introduction and determine if such measurements predict resultant spacial distributions of organisms on adjacent plants or in habitats.

Compare field behavior of wild-type and in vitro constructed strains under variable biological and physical environments in the field.

OUTPUTS:

Test method for estimating fate of GEMs released to plant surfaces.

Journal article on observations on the fate and spatial distributions of GEMs released to plants and soil environments.

Journal article on a comparison of survival, population densities and fate of GEMs released into microcosms and into the field.

Mr. VALENTINE. Mr. Volkmer, do you have any further questions?

Mr. VOLKMER. Yes, it is more of a concern than, I guess, a question, but it is a question in form. Reading from the EPA draft guidelines—these are dated in early May—I find this statement,

> EPA is leaving unanswered for now the question of whether organisms containing genetic material from other organisms in the same genus, for example, products are delivered intergeneric combinations, and those which are developed from a single-source organism, for example, products of undirected mutagenesis organisms with deletions, whether should also be considered new. In the future it is possible that EPA will decide that such arguments are new, but for now they are not subject to PMN requirements.

Ms. HOLLANDER. I take it you want me to comment on that and what the principle is behind it?

Mr. VOLKMER. Is that basically what remains in the guidelines; and is that basically what your interim policy is now? If it is that it is a little different than what I understood you to say earlier.

Ms. HOLLANDER. That is the same as I was saying earlier. As far as I know that is probably what EPA will say in its policy.

I think it illustrates an important point that we tried to make in the testimony that we submitted, which is that we think it is very important to retain flexibility in our policies. We think that the science of biotechnology is evolving very quickly, and we expect it to continue to evolve. We want our policies to be able to adapt to that.

So, in general when you see the policy statement issued you will find a number of statements that will leave room for those kinds of changes in the future, if we decide that they are important and appropriate. We have also established mechanisms for monitoring—we intend to establish mechanisms for monitoring those parts of the industry that are not subject to PMN reporting, so that we will have that kind of information if we need to decide if there is an appropriate change in the future.

Mr. VOLKMER. Well, basically they are not subject to the notice requirements now then, those organisms?

Ms. HOLLANDER. They would not be subject to premanufacturer notification; that is correct. They would be subject instead to notification under section 8(a) of TSCA.

Mr. VOLKMER. So there would still be notification?

Ms. HOLLANDER. Yes, there would.

Mr. VOLKMER. And then you would still review and determine whether or not there is any toxicity problems or whatever, and proceed from there?

Ms. HOLLANDER. Right. It is true that the kind of review under 8(a) is not extensive as a premanufacturing notification review.

Mr. VOLKMER. And 8(a) does not apply to small businesses and R&D?

Ms. HOLLANDER. Section 8(a), I believe, can apply to R&D, but not small businesses.

Mr. VOLKMER. Thank you, Mr. Chairman.

Mr. VALENTINE. Thank you very much, both of you for being with us.

Next we have a panel consisting of Dr. Margaret Mellon, director, Toxics Program, Environmental Law Institute; Dr. Judith A.

Hautala, consultant to the Task Force on TSCA, American Chemical Society; and Mr. Jeffrey N. Gibbs, associate general counsel, Association of Biotechnology Companies; and Ms. Nachama Wilker, executive director, Committee for Responsible Genetics.

Welcome to you with apologies for any names I have mispronounced. The record will show your testimony as you have presented to us. Please feel free to summarize and proceed in any way that you deem appropriate.

So that we might finish today, if you would hold it down to 5 minutes. If you just feel that you can't do that, let us know.

Who goes first?

Dr. Mellon.

STATEMENTS OF DR. MARGARET MELLON, DIRECTOR, TOXICS PROGRAM, ENVIRONMENTAL LAW INSTITUTE; DR. JUDITH A. HAUTALA, CONSULTANT TO THE TASK FORCE ON TSCA, AMERICAN CHEMICAL SOCIETY; JEFFREY N. GIBBS, ASSOCIATE GENERAL COUNSEL, ASSOCIATION OF BIOTECHNOLOGY COMPANIES; AND NACHAMA WILKER, EXECUTIVE DIRECTOR, COMMITTEE FOR RESPONSIBLE GENETICS

Dr. MELLON. I am very pleased to have this opportunity to present my views on H.R. 4452. My brief remarks are confined to the general titles of the bill and the title covering EPA's regulation of engineered organisms.

H.R. 4452 establishes and defines the functions of two extra agency entities intended to coordinate the regulation of biotechnology. The first is the Biotechnology Science Coordinating Committee which is already functioning under an administrative charter. There seems for no need for Congress to mandate the creation of such a committee legislatively, except perhaps to define its functions vis-a-vis other agencies and committees.

The second entity is the Biotechnology Science Research Program. Under the bill the BSRP would be charged with coordinating private and public resources to create a data base to support the review and regulation of biotechnology. The recognition in this bill of the need for the coordination of what we might call regulatory scientific functions is an important contribution to the biotechnology debate. In contrast to the BSCC, the functions of the BSRP are not being performed elsewhere in the Government.

The kind of scientific research functions that the BSRP could undertake are different from the basic research being done in ecological science by NSF and NIH. The BSRP could be doing applied research tailored to and driven by regulatory needs.

One specific task that I think a BSRP could tackle would be the assembly of a database that has as its purpose the reduction of the uncertainty surrounding the nature of the ecological risk associated with the release of genetically engineered organisms. We are now proceeding—wisely, I might add—to regulate these releases without really knowing how large a threat, if any, they pose to the environment.

Many of those who argue for case-by-case review expect that the cautious release of engineered organisms will lead to a better understanding of the risks. In my opinion the case-by-case review will not live up to this expectation unless some entity like the BSRP is specifically charged with compiling a database from which valid conclusions about the impact of an organism can be drawn.

Let me give you an example of what I mean. What if 2 or 3 years from now agencies have approved releases of say 20 or so organisms and no catastrophe has occurred. Will we be able to conclude from such record that all of the releases or some class of them are safe? Unless the releases have been monitored or analyzed to find out what short of catastrophe did happen, I think the answer is no.

The BSRP could establish a program to extract a database from pre- and post-release test data. Such a program might provide, for example, specially designed protocols for monitoring approved releases.

If the BSRP were to compile the data from all the regulatory programs and compile them and analyze them in a systematic way, the result might eventually tell us something about how safe or unsafe the releases of engineered organisms are. This would be an important project and one not likely to be done by program offices, NSF, or BSCS.

I would like to move on now to two specific provisions of H.R. 4452. The first is the definition of genetically engineered organisms.

I am concerned that H.R. 4452 definition of genetically engineered organisms as who those genetic material is derived from more than one taxonomic genera, is too narrow. It excludes from review genetically modified pathogens and organisms capable of degrading substances like lignin and cellulose that are structural components of living cells. Both of these categories of organisms could represent substantial threats if they were to proliferate in the environment.

On the positive side, the definition does not exempt regulatory sequences, as the OSTP policy apparently does. I am concerned that the scientific premise for such an exemption—that the transfer of structural genetic elements will not result in a high degree of novelty—might not be sound.

Transfers of regulatory sequences would seem to permit variations not only in the levels of gene products, but also in the timing of their production, both during the lifetime of the organisms and in relation to other genes. Like notes of music, the same genes might produce quite different melodies if they are played in different sequences or in conjunction with different other genes. The degree of novelty achieved might approach that of organisms with structural genes from taxonomically unrelated organisms.

I am also concerned about EPA's ability in administering such an exemption to assure that regulatory sequences for which the exemption is claimed do not carry additional uncharacterized genetic material.

My last comment is about the permit system that the bill would establish. Whether a permit system like the one mandated by the bill is necessary depends on the adequacy of the program established under existing legislation, specifically under the PMN provisions of TSCA.

My preliminary review of the EPA policy document indicates that EPA has established a well thought out approach, generally satisfactory in terms of data requirements, coverage, and objectives of review. Although it is not perfect, at this point it is in no way so badly flawed that it should be scrapped.

I think that it is time to get on with the regulation of genetically engineered organisms, and that TSCA as implemented in the policy statements will do, but I want to make the following cautionary observation on TSCA's adequacy.

As has been mentioned before today, TSCA provides authority, but TSCA is not licensing statute. TSCA provides authority that if it were used to maximum extent could approximate a stringent licensing system like the one found under FIFRA, but TSCA does not require that that be done. It gives EPA substantial discretion to decide on a product-by-product basis whether to regulate a chemical and how much data to require from applicants to support a regulatory decision.

Therefore the success, or the judgment as to the adequacy of the TSCA program is going to depend a lot on how vigorously EPA exercises its discretionary authority in the case of each organism that it reviews.

I would be glad to answer any questions.

[The prepared statement of Dr. Mellon follows:]

STATEMENT OF

Margaret Mellon
Environmental Law Institute

Before the Subcommittee on Natural Resources, Agricultural Research and the Environment and the Subcommittee on Science, Research and Technology

June 5, 1986

Mr. Chairman and Members of the Subcommittee:

Good morning. My name is Margaret Mellon. I am the Director of the Toxic Substances Program at the Environmental Law Institute. I am pleased to have this opportunity to present my views on the proposed Biotechnology Science Coordination Act H.R. 4452. My brief remarks are confined to the two general titles of the bill and the title covering EPA's regulation of engineered organisms.

I. BSCC and BSRP

H.R. 4452 establishes and defines the functions of two extra-agency entitities intended to coordinate the regulation of biotechnology. The first is the Biotechnology Science Coordinating Committee. A virtually identical committee of the same name is already functioning under an administrative charter. There seems no need for Congress to mandate the creation of such a committee legislatively, except perhaps to define its functions vis a vis other agencies and committees.

The second entity is the Biotechnology Science Research Program. Under the bill, the BSRP would be charged with coordinating private and public resources to create a database to support the review and regulation of biotechnology. The recognition in H.R. 4452 of the need to sponsor regulatory scientific functions is an important contribution to the biotechnology debate. The kind of scientific research functions that the BSRP could undertake are different from, but needed in addition to, the basic research being done in ecological science by NSF and NIH. The BSRP would be doing applied research tailored to and driven by regulatory needs, much of it in the general area of risk assessment. In contrast to the BSCC, the functions of the BSRP are not being performed elsewhere in government.

One specific task that I think a BSRP could tackle would be the assembly of a database that had as its purpose the reduction of the uncertainty surrounding the ecological risk associated with the release of genetically engineered organsms. We are proceeding (wisely I might add) to regulate these releases without knowing the degree of risk, if any, they pose to the environment. Many of those who have argued in the past for case-by-case review expect that the cautious release of engineered organisms will lead to a better understanding of the risks. In my opinion case-by-case review will not live up to this expectation unless some entity like the BSRP is specifically charged with compiling a database from which valid conclusions about the impact of the organism on the environment can be drawn.

Let me give you an example of what I mean.

What if two or three years from now agencies have approved releases of say 20 or so organisms and no catastrophe has occurred. Will we be able to conclude from such a record that all or some class of the releases are safe? Unless the releases have been monitored and analyzed to find out what short of catastrophe did happen, I think the answer is no.

The BSRP could establish a program to extract a database from pre-and post-release test data. Such a program might provide, for example, protocols for monitoring approved releases designed not only to track organisms but also to evaluate their effects. If the BSRP were to compile the data from all the regulatory programs and analyse them in a systematic way, the result might tell us something about how safe or unsafe releases of engineered organisms are. This is would be an important project not within the traditional mission of program offices or NSF.

II. EPA REGULATION

Definition of Genetically Engineered Organism

H.R. 4452 defines genetically engineered organisms as organisms whose genetic material is derived from more than one taxonomic genera. I am concerned that the definition is too narrow. It excludes from review genetically modified pathogens and organisms capable of degrading substances like lignin and cellulose that are structural components of living cells. Both categories of organisms could represent substantial threats if they were to proliferate in the environment.

On the positive side, the definition does not exempt regulatory sequences, as the OSTP policy apparently will. I am concerned that the scientific premise for such an exemption — that transfers of regulatory sequences will not result in a high degree of novelty — might not be sound. Regulatory sequences turn genes on and off and signal where they begin and end. Transfers of regulatory sequences would seem to permit variations not only in the levels of gene products but also in the timing of their production — both during the lifetime of the organisms and in relation to other genes. Like notes of music, the same genes might produce quite different melodies if they are played in difference sequences or in conjunction with different other genes. The degree of novelty achieved might approach that of organisms with structural genes from taxonomically unrelated organisms.

I am also concerned about EPA's ability to assure that any regulatory sequences for which the exemption is claimed do not carry along additional uncharacterized genetic material.

Burden of Proof

H.R. 4452 requires that applicants shall have the burden of demonstrating that their activities will not constitute an unreasonable risk to the health, welfare, and the environment. It is not clear to me what this provision means. If it means that applicants have an obligation in an evidentiary sense to prove that nothing untoward will happen as a result of a particular release, the provision is meaningless because in the current state of scientific uncertainty that burden could not be carried by any applicant. On the other hand, if the provision means that applicants bear the burden of producing and generating sufficient technical information on which EPA can decide whether a risk is unreasonable, the provision would be a very important one. Reliable, comprehensive test data are absolutely essential to high quality decisions on environmental release and applicants are the proper parties to bear the expense of generating them.

Permit System

Whether a permit system like the one mandated by H.R. 4452 is necessary depends on the adequacy of the program established under the existing PMN provisions of TSCA. My preliminary review of the OSTP policy statement indicates that EPA has established a well-thought out approach, generally satisfactory in terms of data requirements, coverage, and objectives of review. Although it is not perfect, it is not so badly flawed that it should not be implemented. But I would make the following cautionary observation on the use of TSCA to regulate genetic engineering. TSCA is not a licensing statute. TSCA provides authority that, if used to its maximum extent, could approximate a stringent licensing system like that found under FIFRA. But TSCA gives EPA substantial discretion to decide on a product-by-product basis whether to regulate a chemical and how much data to require from applicants. Unlike FIFRA, under TSCA EPA can legally simply fail to review organisms. The success of the TSCA program is therefore going to depend on EPA's vigor in exercising its authority in the case of each organism it reviews.

Mr. VALENTINE. Thank you very much, Doctor.

Dr. HAUTALA. My name is Judith A. Hautala, and I am a consultant to the American Chemical Society Task Force on TSCA. I am also managing director of technology operations at Genex Corp. I appear before you today to present the ASC statement on the Biotechnology Science Coordination Act of 1986.

The American Chemical Society supports the intent of this legislation which is to develop a consistent and practical approach for regulating the science of biotechnology and its commercial applications in order to protect human health and the environment. The ACS foresees considerable potential benefits for society in this emerging field.

However, without a stable regulatory framework, without early resolution of jurisdictional questions, and without assurances to the public that protection of human health and the environment are adequately addressed the development of this technology may be hindered to such an extent that its promises may never be realized.

One of the crucial issues affecting this goal is the effective coordination among various Federal agencies involved in regulating the science of biotechnology and its products. However, the American Chemical Society believes it is premature at this time to legislatively mandate a specific mechanism to coordinate the activities among these agencies.

Such a mandate now could create a bottleneck rather than facilitate effective, consistent action. During these early years of development, a better approach would be to let the current coordination mechanism evolve within the executive branch.

The American Chemical Society strongly endorses the establishment of a biotechnology research program to create a database to support the development and regulation of biotechnology. Areas particularly in need of further research include the development of environmental field test methodologies, the detection of genetically engineered organisms in an ecosystem and the monitoring of the survivablity of genetically engineered organisms.

The Society believes, however, that such a research program should be federally funded through existing agency mechanisms, and the BSCC should serve as a forum for the agencies to discuss their research needs and current programs in biotechnology in order to avoid duplication of effort.

Another important issue to address is the definition of a genetically engineered organism. The ACS believes that the proposed definition in H.R. 4452 should be amended to include genetic material derived from pathogenic or ecologically disruptive organisms and organisms whose pathogenicity or ecological impact has not yet been evaluated, even if all material is derived from a single taxonomic genus. Specific language for this amendment is included in the written statement.

In addition, we believe that the definition should only pertain to live organisms and not to dead or inactivated organisms which might be used as delivery systems.

In addressing the issue of a permitting process, the Society believes that there are essentially three categories of genetically engineered organisms which should be assessed under TSCA. The first category includes organisms used in non-contained manufacturing processes and those organisms developed for intentional release into the environment or otherwise to be used in commerce.

The second category includes organisms used as intermediates in contained manufacturing processes.

The third category includes organisms to be released intentionally into the environment solely for noncommercial research at research institutions.

The American Chemical Society supports the concept of a permitting process for genetically engineered organisms to be released intentionally into the environment for commercial, or commercial R&D purposes, or otherwise to be used in commerce, as well as those genetically engineered organisms used in noncontained manufacturing operations.

However, the ACS favors a more flexible permitting system rather than the three-tiered approach proposed in H.R. 4452. A permit should be granted on a case-by-case basis, with each permit specifying limitations such as the size of the test plot and the extent of usage.

As a result, a given product might require several permits in sequence before full commercialization. Informational requirements for permits should include a description of the engineered organisms; what is known about its pathological and ecological effects, as well as its survivability in the environment; and how the release would be performed, including procedures for monitoring.

The ACS recommends, however, that a permit not be required for genetically engineered organisms that are to be used solely as intermediates in contained manufacturing processes, provided, of course, that appropriate containment can be assured. Instead, a notification system should be instituted similar to the premanufacture notification procedure currently in effect for new chemicals under section 5 of TSCA.

In the case of environmental release of organisms used in noncommercial research at research institutions, the ACS proposes the establishment of an institutional permit. Such a permit would be granted to a research institution as a whole thereby eliminating the need for each investigator to interact with EPA separately. The work at such institutions should be conducted according to EPA guidelines, which would incorporate the NIH guidelines as appropriate and be subject to inspection and enforcement by EPA.

The research institution would be required to establish an internal environmental review committee that would approve each specific release. Such a system for noncommercial biotechnology research could be modeled after the licensing process implemented for the use of radioactive materials.

Although the ACS supports a permitting and notification process as outlined above, the Society believes that a provision should be included to grant the Administrator of EPA the authority to waive the permitting or notification requirements after making a determination based on scientific findings that release of certain classes of organisms would not create any unreasonable risk to human health or to the environment.

Mr. VALENTINE. Doctor, please put your finger right there, and we will come back to that.

We have to go vote.

[Recess.]

Mr. VOLKMER [presiding]. The hearing will resume.

Due to the fact that the gentleman from North Carolina, has an emergency at the present time, he won't be with us for a while, so we will proceed.

Dr. Hautala, you may proceed wherever you left your finger.

Dr. HAUTALA. To summarize the Society's position on——

Mr. VOLKMER. Could you pull the mike—— You have to speak almost directly into those before they pick it up. I can hear you but the people in the back won't be able to hear you.

Dr. HAUTALA. All right.

To summarize the Society's position on permits, the ACS supports the implementation of a permitting process to regulate the intentional release of genetically engineered organisms into the environment. However, the Society believes that at this time it is not necessary to enact new encompassing legislation to accomplish this.

Instead, each of the appropriate existing statutes should be amended as necessary to allow a consistent permitting procedure to be instituted for the release of genetically engineered organisms.

That brings me to the final issue of jurisdictional boundaries among Federal agencies. The American Chemical Society maintains that the current boundaries should remain in place and that the statutes should remain use oriented.

Industrial and other environmental applications of genetically engineered organisms not covered by any other statute would be covered under the jurisdiction of the Toxic Substances Control Act, as they are now for new chemicals.

In order to remedy regulatory deficiencies within the agencies, the ACS also recommends that the following changes be made to H.R. 4452. First, USDA's statutory authorities to regulate plants, plant pests, animals, animal biologicals and animal drugs, should be amended to maintain consistency with the recommendations that the Society has proposed to amend TSCA. Thus a permitting system for the intentional environmental release of genetically engineered organisms should be established as well as institutional permits for noncommercial research involving environmental release.

The ACS believes that the proposed language to amend FIFRA under title 5 of the bill is confusing. If the intent of the amendment is to make genetically engineered organisms ineligible for the R&D exemption from experimental-use permits then the ACS supports the change.

However, if the proposal is intended to regulate all genetically engineered pesticides under TSCA, though nongenetically altered pesticides would be regulated under FIFRA, then the ACS would not support the amendment.

In summary the American Chemical Society supports the intent of H.R. 4452, to give Federal agencies legislative authority under current statutes to regulate the products of biotechnology, to clarify jurisdictional discrepancies among these agencies, and to establish a consistent approach to regulation of biotechnology products.

However, the ACS also believes that the legislative objectives may best be achieved by incorporating the alternative strategies that have been suggested.

Thank you for offering the society the opportunity to express its views. I would be pleased to answer any questions.

[The prepared statement of Dr. Hautala follows:]

STATEMENT

OF

DR. JUDITH A. HAUTALA
ON BEHALF OF THE

AMERICAN CHEMICAL SOCIETY

TO THE
SUBCOMMITTEE ON NATURAL RESOURCES,
AGRICULTURE RESEARCH AND THE ENVIRONMENT

AND

SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY

COMMITTEE ON SCIENCE AND TECHNOLOGY

U.S. HOUSE OF REPRESENTATIVES

ON THE

BIOTECHNOLOGY SCIENCE COORDINATION ACT OF 1986

THURSDAY, JUNE 5, 1986

Chairmen and Members of the Subcommittees:

My name is Judith A. Hautala. I am a consultant to the American Chemical Society's (ACS) Task Force on TSCA and Managing Director of Technology Operations at Genex Corporation. I appear before you today to present the ACS statement on the Biotechnology Science Coordination Act of 1986, H.R.4452.

The American Chemical Society supports the intent of this legislation which is to develop a consistent and practical approach for regulating the science of biotechnology and its commercial applications in order to protect human health and the environment. The ACS foresees considerable potential benefits for society in this emerging field, with promising applications in medicine, agriculture, industry, and environmental protection. However, without a stable regulatory framework, an early resolution of jurisdictional questions, and the assurances to the public that protection of human health and the environment are adequately addressed, the development of this technology may be hindered to such an extent that its promises may never be realized.

In addressing H.R.4452, the Society wishes to highlight several points:

- The ACS believes that a statement of the potential benefits that biotechnology has to offer to society should be included at the beginning of the legislation. In addition, while acknowledging the potential risks associated with some facets of biotechnology, the bill should also stress the fact that in developing a regulatory framework such risks need to be evaluated in relation to economic and other societal benefits.

- Actions and research efforts among the various federal agencies involved in regulating the science of biotechnology and its products should be coordinated as necessary. However, it is premature at this time to mandate legislatively a specific mechanism. Such a mandate now could create a bottleneck rather than a mechanism that facilitates effective, consistent action. During these early years, a better approach would be to let the coordination mechanism evolve within the executive branch.

- Research is needed to evaluate the potential risks associated with individual biotechnology activities and to serve as the basis for regulatory decisions in this area. This is particularly true in the area of predictive ecological methodologies. The American Chemical Society believes that such research to develop and validate these methodologies should be funded primarily by the federal government, though industry should be encouraged to be an active participant. For the immediate future, existing agency mechanisms should fund research in this area. The current Biotechnology Science Coordinating Committee (BSCC) should serve, however, as a forum for agencies to communicate their research needs and directives, and to avoid duplication of effort.

- The ACS supports the implementation of a permitting process to regulate the intentional release of genetically engineered organisms into the environment. However, in order to accomplish this goal it is not necessary at this time to enact new encompassing legislation for the regulation of biotechnology as a whole. Instead, each of the appropriate existing statutes should be amended as necessary to allow a consistent permitting procedure to be instituted for the release into the environment of genetically engineered organisms.

- The American Chemical Society maintains that the statutes should remain use-oriented and that the current jurisdictional boundaries among the federal agencies should remain in place. Thus, the Food and Drug Administration (FDA) would continue to regulate food, drugs, and cosmetics under the Federal Food, Drug, and Cosmetic Act; the Department of Agriculture (USDA) would regulate plants, plant pests, animals, and animal drugs under current statutes such as the Plant Pest Act and the Virus-Serum-Toxin Act; and the Environmental Protection Agency (EPA) would regulate pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Industrial and other environmental applications of genetically engineered organisms not covered by any other statutes would be covered under the jurisdiction of the Toxic Substances Control Act (TSCA).

The following comments on H.R.4452 focus on specific issues of particular concern to the Society.

Title I -- Biotechnology Science Coordinating Committee (BSCC)

The ACS supports the concept of the BSCC to coordinate the review and assessment by the various federal agencies of information regarding genetically engineered organisms. However, in view of the newness of the field of biotechnology and the emerging regulatory matrix that is being developed, the Society believes it is too early in the process to mandate legislatively the creation of any single, comprehensive coordinating body. The specific mechanism, including the composition of the committee as well as where it will be housed, needs to evolve over time as the agencies gain experience from implementing their regulatory frameworks. In the interim, the ACS believes that the currently operating BSCC should be able to address adequately near-term problems and issues.

Title II -- Biotechnology Science Research Program

The American Chemical Society strongly endorses the establishment of a biotechnology research program to create a data base to support the development and any necessary regulation of biotechnology. However, the Society believes that such a research program should be federally funded through existing agency mechanisms. In the interim, the agencies should communicate through the BSCC to discuss their research needs and current programs in biotechnology. Areas particularly in need of further research include the development of environmental field test methodologies, the detection of genetically engineered organisms in an ecosystem, and the monitoring of the survivability of genetically engineered organisms.

Title III - EPA Regulations--Amending the Toxic Substances Control Act (TSCA)

The ACS supports the amendments to TSCA proposed in Title III that grant EPA statutory authority to regulate those products of biotechnology that, based on use, would be regulated under TSCA.

a. Permits

From a regulatory perspective, the Society believes that there are essentially three categories of genetically engineered organisms under TSCA: (1) organisms used in noncontained manufacturing processes and those organisms developed for intentional release into the environment or otherwise to be used in commerce; (2) organisms used as intermediates in contained manufacturing processes; and (3) organisms to be released intentionally into the environment solely for noncommercial research at research institutions.

The American Chemical Society supports the concept of a permitting process for those genetically engineered organisms to be released intentionally into the environment (including those to be used for commercial research and development) or otherwise to be used in commerce, as well as for those to be used in noncontained manufacturing operations (category 1). However, the ACS favors a more flexible permitting system rather than the proposed three-tier approach. A permit should be granted on a case-by-case basis, with each permit specifying limitations such as the size of the test plot and the extent of usage. A given product might require several permits in sequence before full commercialization. Informational requirements should include a description of the engineered organism, what is known about its pathological and ecological effects as well as its survivability in the environment, and how the release would be performed, including procedures for monitoring.

The ACS recommends, however, that a permit not be required for genetically engineered organisms that are to be used solely as intermediates in contained manufacturing processes (category 2), provided appropriate containment can be assured. Instead, a notification system similar to the premanufacture notification (PMN) procedure (Section 5 of TSCA) currently in effect for new chemicals should be instituted. The notification requirements would include a full description of the organism; and information on containment features of the manufacturing process, the process for inactivating the organisms (including data on inactivation), and mechanisms and procedures relevant to controlling the organisms in the event of accidental release from the containment equipment. The ACS believes that such a notification procedure (which treats these organisms essentially as chemical intermediates) will be sufficient in light of past experience with contained manufacturing.

In the case of the environmental release of organisms used in noncommercial research at research institutions (category 3), the ACS proposes the establishment of an institutional permit. Such a permit would be granted to a research institution as a whole, thereby eliminating the need for each investigator to interact with EPA separately. In applying for a permit, these institutions would need to specify the range of research intended, including the organisms to be released, the nature of the field test, and the appropriate controls. The research institution would be required to establish an internal environmental review committee that would approve each specific experiment. The work at such institutions should be conducted according to EPA guidelines which would incorporate the NIH guidelines as appropriate, and would be subject to inspection and enforcement by EPA.

Such a system for noncommercial biotechnology research at research institutions could be modelled after the licensing process implemented for the use of radioactive materials. In these cases, an institutional permit is granted which specifies the isotopes that can be used and at what levels. In addition, an internal safety committee must be established to develop a set of rules for the use of these materials at the institution.

b. Definition

The proposed definition of a genetically engineered organism should be amended to include material derived from pathogenic organisms and organisms whose pathogenicity has not yet been determined. Therefore, the definition under Section 32, Subpart (b) should read: "For purposes of this section, the term 'genetically engineered organism' means a bacterium, virus, fungus, plant cell, plant tissue, animal cell, or animal tissue which has been deliberately altered to contain genetic material either derived from more than one taxonomic genus or from pathogenic or ecologically disruptive organisms or organisms whose pathogenicity or ecological impact has not yet been evaluated, and which is not expressly regulated under Section 401 of the Biotechnology Science Coordination Act of 1986 or under any other Federal law."

Furthermore, the definition should pertain only to "live" organisms and not dead organisms which might be used as delivery systems but which have been inactivated.

c. Worker Safety

The Society believes that worker safety is an important consideration that should not be overlooked in the regulation of biotechnology. The ACS recommends that if in evaluating a permit or notification request the EPA (or any other agency) believes there is a serious worker safety issue, then the case (along with the agency's concerns) should be referred to the Occupational Safety and Health Administration for its review and action.

d. Biotechnology Advisory Panel

A biotechnology advisory panel should be established, but it should be modeled after EPA's FIFRA Science Advisory Panel (SAP), which has been operating successfully. The panel should address generic issues and should not, on a routine basis, examine individual applications. Applications could be referred to the panel for review at the discretion of the Administrator or at the request of the applicant.

e. Waivers

As more experience and information are gained with a wider variety of organisms, it should be possible to make judgments on the safety of certain classes of genetically engineered organisms. Therefore, the American Chemical Society believes that a provision should be included in the legislation granting the Administrator of EPA the authority to waive the permitting or notification requirements after making a determination, based on scientific findings, that release of the organism would not create any unreasonable risk to human health or to the environment.

f. Grandfathering

Biotechnology itself is not new; some areas such as fermentation technology have been used for centuries and have a long safety record. The ACS is concerned about the status of such established commercial applications of microorganisms, for example, those used presently to produce enzymes. The Society suggests that the need for grandfathering these organisms be considered. As was the case in compiling the original TSCA Inventory, companies should be allowed to report the use of organisms already in commerce. The companies should not be subject to the additional requirements of "new" organisms, unless there is a finding of unreasonable risk to human health or to the environment.

g. EPA Response Time

Establishing a permitting process shifts the burden of proof that there will be no unreasonable risk to human health or to the environment from EPA to the applicant. However, the ACS believes that a timeframe should be imposed that requires the Agency to make a decision within a specified period after an application is submitted. For instance, it would be difficult to analyze results from the previous growing season, apply for a permit, and allow 90 days before Spring planting. However, a shorter timeframe (45 days, for example) would provide the Agency adequate time to complete a review and still allow a company to complete Spring planting.

Title IV -- USDA Regulations

The ACS believes that USDA's statutory authorities to regulate plants, plant pests, animals, animal biologicals, and animal drugs should be amended to establish a permitting system for the intentional environmental release of genetically engineered organisms. A flexible permitting approach as was described earlier for TSCA is recommended for commercial release. Likewise, institutional permits should be established for noncommercial research involving environmental release.

As recommended earlier for TSCA and in order to maintain consistency, the definition of which organisms are subject to regulation should be amended. Similarly, an internal USDA biotechnology advisory committee should be established and modeled after the EPA SAP.

Title V -- Conforming Amendments

FIFRA

The American Chemical Society believes that the proposed language to amend FIFRA under Title V of the bill is confusing. If the intent of the amendment is to make genetically engineered organisms ineligible for the R&D exemption from experimental use permits, then the ACS supports the change. However, if the proposal is intended to regulate all genetically engineered pesticides under TSCA, while nongenetically altered pesticides would be regulated under FIFRA, then the Society would not support the amendment. The ACS believes that the statutes in question should be kept use-oriented. TSCA was established to fill in the gaps of existing laws, and as such, should serve the same function in relation to the regulation of genetically engineered organisms. FIFRA should retain its statutory authority over all pesticides whether genetically engineered or not. FIFRA should be amended only to make it consistent with the previous recommendations to amend TSCA.

In summary, the American Chemical Society supports the intent of H.R.4452--to give federal agencies legislative authority under current statutes to regulate the products of biotechnology, to clarify jurisdictional discrepancies among these agencies, and to establish a consistent approach to the regulation of biotechnology products. However, the ACS believes that the legislative objectives may best be achieved by incorporating the alternative strategies suggested in this testimony.

Mr. **Volkmer**. Thank you, Dr. Hautala, we will hold questions until we hear from the whole panel.

Mr. Gibbs, you may proceed.

Your statement along with the other statements will be made a part of the record, verbatim, at this point in the record.

Mr. **Gibbs**. I would like to just summarize a few of the principle points of the statement since it has been introduced into the record.

The first point that I would like to make is to emphasize that the Association of Biotechnology Companies and 150 members, are committed to assuring that products developed through biotechnology are safe. This commitment extends to all biotechnology derived products, from drugs, such as interferon, use to prevent or treat diseases, to bioengineered organisms that are now underdevelopment to clean up toxic waste sites.

In its broadest sense biotechnology is a quite old, dating to earliest fermented drinks and hybridized grains. But in its newest sense, encompassing highly sophisticated techniques for manipulating genetic materials, such as hybridomas and recombinant DNA, biotechnology is in its infancy.

Correspondingly, the companies that are utilizing this new biotechnology often are very small and not well-established. The bulk of the companies that are dedicated solely or principally to making products through the use of biotechnology have only between 25 and 100 employees. Even the largest biotechnology company, Genetech, has fewer than 1,000 employees.

Moreover, most of these companies are not financially strong. They have growth of a few products on the market; many companies are still early in the research and development stage.

For these reasons, we fear that the Biotechnology Science Coordination Act of 1986 could severely jeopardize the ability of the biotechnology industry to maintain its present high level of creativity and innovativeness. As proposed, the legislation would introduce substantial new barriers to market entry for biotechnology companies, particularly ones that are developing products that have environmental or agricultural applications.

Few companies would have the financial and regulatory wherewithal to take a new product to market under the regulatory scheme contemplated by the proposed legislation.

The bill is fairly complex. Rather than going through point by point, I would just refer members of the committee to the prepared testimony. But there are a couple of general points that I think are very important to make in the context of considering this proposed legislation.

The first one is that biotechnology is still in its infancy. The underlying science, such as molecular biology and cellular genetics, are growing and changing rapidly.

The understanding of scientists is constantly evolving. The biotechnology industry itself is similarly in constant flux; therefore, flexible regulation is crucial to the long-term health of the industry. Whatever regulations are put in place—and ABC endorses the concept of Federal regulation of release of the bioengineered microbes into the environment—must not be rigid; instead the regulations must be capable of being adapted to new circumstances and new technological developments.

For example, when recombinant DNA research was first publicized in the mid-1970's, many people called for either a halt of the research or severe restrictions on it. If legislation had been enacted that would have imposed those sorts of restrictions, we would still be without, in all likelihood, human growth hormone, human insulin product, and interferon A.

The development of numerous other products, such as malaria and herpes vaccines, which are currently being tested and developed at this moment, would have been substantially impeded. Fortunately, legislation was not enacted; instead, the National Institutes of Health promulgated regulations which have been widely followed and generally considered as very successful.

As more experience was gained with recombinant DNA research, the regulations have been relaxed. The Netherlands, however, were not as fortunate as the United States; the Netherlands imposed severe restrictions on recombinant DNA research, and for several years there was essentially no research taking place in that country.

According to a very recent Department of Commerce study, the Dutch still have not regained the ground that they lost during that halt in testing 10 years ago.

Legislation is just simply not as flexible as regulation by Federal agencies. Once standards are legislatively established, they become very difficult to undo. Even assuming that the bill reasonably addresses the principal issues raised by the science of 1986, it may be seen as anachronistic in just a few years.

A second fundamental consideration must be kept in mind. That is that biotechnology is international. In 1984, the Office of Technology Assessment released a report to the House Committee on Science and Technology analyzing the competition in biotechnology between the United States, Japan, and Europe. The report concluded that the United States had a lead in biotechnology but that this advantage was endangered. Since then the edge enjoyed by the United States has narrowed further.

Environmental regulations were cited by OTA as a factor imperiling the United States' competitive advantage. Enacting new legislation that would impose even greater restrictions on U.S. biotechnology companies would only further erode our competitive position.

Research and testing of genetically engineered organisms will still continue, only they will continue abroad. Ultimately, this trend could mean a substantial loss of U.S. jobs once biotechnology becomes integrated into basic industries such as chemical and electronic manufacturing. It is only a matter of time before biotechnology does become part of all basic manufacturing, from chemicals, to foods, to food additives.

As far as the specific comments on the bill, I would simply refer to the material that we submitted earlier. There is one other point, though, that I think is extremely important, and that has to do with product liability insurance.

We were asked in our invitation to testify, to comment on a proposal that product liability insurance be required of all companies that had or intended to release bioengineered organisms into the environment. I think that it is extremely important that we keep in mind that product liability insurance is a national problem.

The cost of insurance has escalated for all sectors of the economy. Everyone is affected, including Coney Island, the Federal Government, local little leagues, midwives, doctors, lawyers; biotechnology is no exception.

There is simply no rationale to single out the biotechnology industry and biotechnology companies with the restriction that they possess insurance as a prerequisite to conducting business. The effect of such a requirement would be to reduce, if not eliminate, environmental releases in the United States of bioengineered organisms.

The long-range consequences of precluding environmental releases could be most unfortunate. Although biotechnology derived products have thus far been concentrated in health care, many of the most important long-term applications in biotechnology will be in the agricultural and environment areas.

Biotechnology has many promises to offer. The Association of Biotechnology Companies and members are committed to assuring the safety of biotechnology derived products as they enter the marketplace and while they are being tested.

But in seeking to minimize the risks associated with biotechnology, we must not foreswear the benefits. Biotechnology has the potential to benefit numerous products and industries.

The value of biotechnology derived products has been estimated by the Department of Commerce to increase sevenfold in the next 5 years. The United States must not, by adopting legislation or regulation, take steps that would cause this enormous potential to go unrequired.

On behalf of the Association of Biotechnology Companies, I would like to thank the committee for affording us this opportunity to present our views. I would be happy to answer any questions.

[The prepared statement of Mr. Gibbs follows:]

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STATEMENT

BY

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ASSOCIATE GENERAL COUNSEL

ASSOCIATION OF BIOTECHNOLOGY COMPANIES

BEFORE THE

SUBCOMMITTEES ON NATURAL RESOURCES,

AGRICULTURAL RESEARCH AND ENVIRONMENT

AND ON SCIENCE, RESEARCH, AND TECHNOLOGY

United States House of Representatives

on the

Proposed Biotechnology Science Coordination

Act of 1986, H.R. 4452

Thursday, June 5, 1986

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Mr. Chairman and Members of the Subcommittee on Natural Resources, Agricultural Research and Environment, and the Subcommittee on Science, Research and Technology.

My name is Jeffrey Gibbs. I am Associate General Counsel to the Association of Biotechnology Companies (ABC). On behalf of ABC and its members, I wish to express our appreciation for this opportunity to present our views on a subject that is of considerable importance to the biotechnology community.

The Association of Biotechnology Companies is the largest organization of biotechnology companies in the world. ABC was founded in December 1983, by nine small biotechnology companies that saw the need for an organization that could represent their common interests and speak for the biotechnology industry. Today, the Association has over 150 members, ranging from small companies that have just entered the biotechnology field to established companies that are already marketing products that utilize biotechnology. ABC's members also include research institutions, governmental organizations, and companies that service the biotechnology industry. Reflecting the worldwide nature of biotechnology, ABC has a growing international membership and has developed liaisons with biotechnology groups overseas. (A list of current ABC members is attached.)

At the outset, I wish to emphasize that ABC, its members, and the biotechnology industry are committed to ensuring that products developed through biotechnology are safe. This commitment extends to all biotechnology-derived products, from health care products used to prevent or treat diseases, to bioengineered organisms under development to clean toxic waste sites. Consistent with this commitment to safety, ABC and its members have worked closely with the Environmental Protection Agency, the United States Department of Agriculture, and the Food and Drug Administration to resolve safety and effectiveness issues presented by biotechnology-derived products.

Yet, while ABC is fully committed to ensuring the safety of biotechnology-derived products, we are concerned by the costs of excessive regulation. It is well recognized that unduly burdensome safety regulations impose a real economic cost by raising product prices, decreasing innovation, and impairing competitiveness with foreign companies. This is true even for mature industries. It is especially true for nascent industries that lack a positive cash flow or sound financial base.

In its broadest sense, biotechnology is quite old, dating to the earliest fermented drinks and hybridized grains. In its newest sense -- encompassing highly sophisticated techniques for manipulating genetic materials, such as recombinant DNA and hybridomas -- biotechnology is in its infancy. Correspondingly, the companies that are utilizing these "new" biotechnology processes generally are very small and not well established. The bulk of the biotechnology companies have only between 25 and 100 employees. Even the largest biotechnology company, Genentech, has fewer than 1,000 employees.

Nor are these companies financially strong. Most companies still do not have even a single commercial product. Many are at a very early stage of research and development. Often, the companies have little more than a new concept or new process.

Considering their short history, the biotechnology companies have been extraordinarily innovative. Dozens of new biotechnology-derived medical devices, human drugs, and animal biologics are already being marketed. Literally hundreds of other new products are currently under research. Many biotechnology companies will be unable to bring their new ideas to fruition, however, if the costs of market entry become too high.

For this reason, we fear that the Biotechnology Science Coordination Act of 1986, H.R. 4452, could severely jeopardize the ability of the biotechnology industry to maintain its present level of productivity and creativity. As currently proposed, the legislation would introduce substantial new barriers to market entry for biotechnology companies, particularly ones that are developing products to improve the environment or agricultural practices. Few companies would have the financial and regulatory resources to take a new product to market under the regulatory scheme contemplated by the proposed legislation.

H.R. 4452 is long and complex. Rather than analyzing it section by section, I would prefer to discuss a few of the provisions that are of particular interest to ABC and its members.

First, however, I believe that a few general observations are in order. As I noted before, the use of recombinant DNA and hybridomas for commercial purposes is a very recent development. Biotechnology is still in its infancy. The underlying sciences, such as molecular biology and cellular genetics, are also growing and changing rapidly.

The biotechnology industry itself is in constant transition. Flexible regulation is crucial to the long-term health of the industry. Whatever regulation is put in place -- and ABC endorses the concept of federal regulation of releases of bioengineered microbes into the environment-- must not be rigid, but must instead be capable of adapting to new circumstances and new technological developments.

For example, when recombinant DNA experiments first became publicized in the mid-1970s, many people called for federal legislation to regulate the research. Such a law could have substantially inhibited recombinant DNA research. If the law had passed, we probably would be without human growth hormone and human insulin. The development of numerous other important products, such as malaria and herpes vaccines, would have been impeded. Fortunately, legislation was not enacted; instead, the National Institutes of Health issued stringent guidelines. As researchers and government agencies acquired more experience with recombinant DNA research, the guidelines were relaxed.

Legislation, though, is not as flexible as regulation by federal agencies. Once standards are legislatively established, they become very difficult to undo. Even assuming that the Biotechnology Science Coordination Act of 1986 reasonably addresses the principal issues raised by the science of 1986, it may be seen as anachronistic in just a few years. For that reason, ABC would strongly prefer that government oversight and control be accomplished through regulations issued by federal agencies, rather than a statute that could "freeze" a science that is swiftly evolving.

There is a second fundamental consideration that must be kept in mind, too. Biotechnology is international. In 1984, the Office of Technology Assessment released a report to the House Committee on Science and Technology analyzing the competition between the U.S., Japan, and European countries. The report concluded the United States had a lead in biotechnology, but that this advantage was endangered. Since that time, the edge enjoyed by the United States has narrowed further.

The existing environmental regulations were cited by OTA as a factor imperiling the United States' competitive advantage. Enacting new legislation that would impose even greater restrictions on U.S. biotechnology companies would only further erode our competitive position. Research and testing of genetically-engineered organisms will continue, only it will continue abroad. For years, we have heard of the "drug lag." If unduly burdensome regulation of bioengineered organisms occurs in the United States, we will soon be investigating a "biotechnology lag," in which other countries are deriving the benefits of biotechnology long before the United States. This trend will mean in the short run the loss of American technology as U.S. companies license processes and products to foreign companies. Ultimately, it could cause a substantial loss of U.S. jobs, once biotechnology becomes integrated into basic industries, such as chemical and electronic manufacturing.

The Office of Technology Assessment report on international competition in biotechnology also noted that regulatory uncertainty tends to discourage commercialization of biotechnology. ABC fears that H.R. 4452 could, at least in the near term, have precisely that effect.

New legislation, no matter how well drafted, often raises novel questions of interpretation and implementation. The full import of a new law often becomes clear only after several years of experience with the legislation by the implementing agencies and affected industry. Because of the complexity of the subject matter and of the Bill itself, H.R. 4452 could deter some commercial applications of biotechnology. It would almost certainly cause a shift away from environmental and agricultural applications, which would be most heavily affected, and into health products.

Applying the existing environmental statutes to biotechnology, by contrast, have a much lower inhibitory effect on biotechnology research and development. Even if these laws were not drafted for the specific purpose of regulating biotechnology, they are now familiar to all concerned. The experience gained with these statutes ensures a far shorter learning curve when they are applied to biotechnology than for new legislation directed specifically at biotechnology. ABC believes that the costs of uncertainty associated with new legislation must be carefully weighed by Congress.

Turning specifically to the Bill, we believe that Title I, which establishes a Biotechnology Science Coordinating Committee, is largely unnecessary. Because the BSCC must maintain considerable flexibility in defining its role and responding to issues, we prefer that this body be created by regulation. Section 102(c) not withstanding, ABC also fears that the tasks assigned to the BSCC, such as promoting uniformity in product reviews, virtually ensure that product approvals will be delayed.

One substantive aspect of Title I that is especially troublesome is requiring the BSCC to develop good laboratory and good manufacturing practices "in the biotechnology sciences." The term "biotechnology sciences" is not defined. Indeed, it may defy definition, for biotechnology is not a science, but a process.

More important, good manufacturing practice (GMP) requirements vary considerably, depending on the type of product. For example, FDA's drug GMP regulations differ considerably from its food GMP regulations. Both sets of regulations have proven to be effective in dealing with a wide range of issues within that product class, but each product class raises entirely separate GMP questions. It will be extremely difficult to craft GMP regulations that are equally valid for all products which are biotechnology-derived. Imposing a second set of GMP requirements that apply only to products manufactured with "biotechnology sciences" will also result in redundant and confusing regulation.

Indeed, drafting any set of biotechnology GMPs that would not be completely outdated at the time of promulgation would be very difficult. A far better approach is FDA's "Points to Consider" documents. These are guidelines drafted by scientists that incorporate the latest scientific knowledge regarding biotechnology. Because they are guidelines, they can easily be revised as the technology advances. The Points to Consider documents have been widely regarded as successful, largely because of their considerable flexibility. Good manufacturing practice regulations could never provide the same degree of adaptability.

Turning to Titles III and IV of the legislation, a principal concern of ABC is the multiple stages of review. Before any "genetically-engineered organism" can be released into the environment or used in manufacturing, three separate applications must be filed. By itself, this could impose a significant regulatory cost for companies, even though the specific product or microbe entails little risk. Furthermore, H.R. 4452 does not establish any time limits for EPA or USDA review of an initial use permit. Without a statutory deadline, the review could last indefinitely, effectively killing the product.

Nor does the proposed legislation distinguish between the initial use permit and the expanded use permit. It is very difficult to tell why there are two discrete research phases, or how those phases differ. Requiring two experimental phases with two sets of submissions will substantially increase the research costs and delay product introduction. Although the Bill does contemplate a waiver of the second research stage, the procedural prerequisites, such as publication in the Federal Register for public comment, virtually guarantees that few waivers will be granted.

Moreover, the evidentiary burden upon the applicant is extremely high. It is the applicant's burden to demonstrate "that the activities in question will not constitute an unreasonable risk to human health, welfare, or the environment." Those terms are not defined in H.R. 4452. Without balanced criteria for determining whether a product constitutes an "unreasonable risk," the applicant could effectively be required to perform an almost impossible task: showing that the product is totally free of risk.

Once a permit is issued, the Administrator of EPA and the Secretary of the USDA may revoke or modify that permit, at any time, if they determine that the product constitutes an "unreasonable risk." No standards are prescribed, nor appeal procedures established. Thus, even after having extensively tested the genetically-engineered organism and submitted three separate applications, a company is still afforded no protection against an agency decision to rescind the approval.

A related difficulty with Titles III and IV is that they add many more procedural hurdles before a product can be commercialized. Each hurdle costs time and money. Each hurdle also increases the risk that a safe and beneficial product will never reach the market for purely procedural reasons.

A number of suits already have been filed to block or delay environmental releases. These suits have been predicated on procedural objections, not actual evidence of risk. The intricate procedural scheme established by H.R. 4452 would not only mean more barriers to obtaining USDA and EPA approvals, but raises the likelihood of third party suits relating solely to procedural issues.

Moreover, H.R. 4452 does not clarify the relationship between federal review, and state, county or municipal regulation of bioengineered organisms. If the exhaustive EPA and USDA review procedures do not preempt local regulation, the costs and delays for manufacturers will multiply further a corresponding incremental gain to public safety.

We also seriously question the need to limit the effective period of an approval to three years. This limitation can only lead to great uncertainty by companies in trying to develop business plans. This three-year limitation is not attached to drugs, devices, food additives, or new chemicals. ABC does not believe that it is reasonable to place an initial three-year limit on a drug product that was manufactured with a "genetically-engineered organism," when its conventional counterpart remains on the market until specific safety problems become known.

One other aspect of H.R. 4452 warrants specific mention because of its potentially adverse repercussions. The proposal regulates releases of bioengineered organisms by academic researchers to the same degree and in the same manner as commercial enterprises. That restriction could ultimately have a highly deleterious effect. As the Office of Technology Assessment noted, many of the major advances in biotechnology have resulted from research at universities. The innovativeness and creativity of the universities has been fostered by the limited amount of regulation researchers have encountered. H.R. 4452, however, will impose the same comprehensive regulatory requirements on university researchers as large commercial enterprises. The results will be predictable: academic research on bioengineered-organisms in the United States will become a rarity. The costs of full regulatory compliance will be unaffordable for non-profit institutions. The same restrictions, though, will not exist abroad, and the next round of scientific breakthroughs will occur in Japan, Europe, Canada, and elsewhere.

To summarize, while ABC supports federal regulation of biotechnology, we doubt whether legislation is the appropriate vehicle. Because of the rapid changes in the biotechnology industry and in its scientific underpinnings, the greater flexibility of agency regulation offers many advantages. Furthermore, we also have substantial questions regarding specific provisions of H.R. 4452.

The final point that we wish to address was raised in the letter inviting ABC to testify at this hearing. We were asked whether the federal government should require that all companies intending to initiate environmental releases have liability insurance. ABC is unequivocally opposed to such a requirement.

Products liability is a nationwide problem. The costs of insurance have escalated for all sectors of the economy. Everyone is affected, including Coney Island, the federal government, local Little League teams, midwives, police departments, and school systems, to name a few. Biotechnology is no exception.

As is true for these other sectors, biotechnology companies have had an increasingly difficult time in securing products liability insurance at an affordable cost, or at any cost. The current problems of biotechnology companies in obtaining liability insurance far transcend the biotechnology industry. (For this reason, ABC is developing an insurance and risk minimization program for biotechnology companies.) The scarcity of insurance even affects biotechnology companies that would not be covered by H.R. 4452, but are using intra-generic bioengineered organisms to manufacture devices and drugs.

Under these circumstances, there is simply no rationale for singling out the biotechnology industry for the restriction that they possess insurance as a prerequisite to conducting business. Indeed, to date the biotechnology industry has enjoyed an exemplary safety record.

The effect of such a requirement would be to reduce, if not eliminate, environmental releases in the United States of bioengineered organisms. Environmental release insurance now is virtually unavailable. Insurance companies have essentially ceased writing new environmental policies, even for the largest chemical manufacturers.

The long-range consequences of precluding environmental releases could be most unfortunate. Although biotechnology-derived products have thus far been concentrated in health care, many of the most important long-term applications of biotechnology will be in the agricultural and environmental areas. Indeed, one promising avenue of exploration is the use of genetically-engineered organisms to remove chemicals and toxins that were introduced into the environment in the first instance by conventional chemical manufacturing. The problems created by these chemicals, however, now virtually preclude biotechnology companies from obtaining insurance against environmental risks. It would be ironic if this unavailability of insurance caused by conventional chemicals were to prevent researchers from determining whether biotechnology could correct the environmental problems created by the chemicals.

Biotechnology has many benefits to offer, from new life-saving drugs to new agricultural products that could replace synthetic chemicals. Establishing an insurance requirement, however, will probably mean that many of those benefits will not be enjoyed by the American public. Given the lack of insurance generally and the composition of the biotechnology industry, an insurance requirement could effectively bar many new, beneficial biotechnology-derived products from the United States.

On behalf of the Association of Biotechnology Companies, I would like to thank the Committees for affording us this opportunity to present the views of the Association and its members on this critical issue.

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CURRENT AS OF DECEMBER 10, 1985

Mr. VOLKMER. Thank you very much, Mr. Gibbs.

Ms. Wilker.

Ms. WILKER. My name is Nachama Wilker; I am the executive director of the Committee for Responsible Genetics. The Committee for Responsible Genetics is a national nonprofit organization of scientists public health and public policy professionals, and others dedicated to the development of biotechnology in a safe and socially responsible manner. We appreciate the opportunity to appear before these two subcommittees to share our comments with you today on the Biotechnology Science Act of 1986.

While the promise of biotechnology can be presented as almost limitless, this potential is inevitably accompanied by some of the same types of risks associated with chemical technologies. The risk associated with biotechnology however, has a set of significant characteristics that distinguish it from chemical technologies.

Chemical substances do not reproduce themselves. Biological organisms, on the other hand, have the potential to reproduce and thus to proliferate in our environment and to mutate further and recombine with other organisms already present in the ecosystem.

From our past experience with the inadvertent introduction of organisms such as the gypsy moth and the citrus canker, we have learned how difficult it is to eradicate organisms once they have established themselves in the environment. And unlike exploding automobiles, our mistakes in this area will be very difficult to recall.

Today we would like to address our comments to areas of the bill. First, to the community notification process in the regulation of environmental release; and second, the development of fundamental research programs that support risk assessment, risk management, and large databases.

The Committee for Responsible Genetics strongly supports the development and implementation of a community notification process as discussed in the bill. Local residents are familiar with the ecology and history of their own communities.

They may possess critical information that is not available to the regulating agency or the manufacturer that could bear on the results of the release of a particular organism into that community. The bill's proposed notification process, while a step in the right direction, is insufficient.

Four weeks will not allow enough time for a informational exchange, a proper risk communication and education within the community. Three months' time would be more sufficient.

We also recommend that in notifying local officials and planning bodies that section 9(b) of the initial use permit section be amended to include notification of environmental bodies and, where possible, institutional biosafety committees.

The Committee for Responsible Genetics commends the steps in the bill toward addressing inadequacies of our existing scientific base of knowledge and to deal with the questions raised by the release of genetically altered organisms into the environment. Critical questions, however, remain to be answered in the areas of risk assessment, physical and biological containment.

Our techniques for monitoring of organisms once released into the environment remain at a primitive stage of development. Fundamental research will be very important for risk assessment purposes and should be done by our most qualified scientists.

We recommend this research be conducted under the auspices of the National Science Foundation rather than the bill's recommendation of the Office of Science and Technology Policy. We make this recommendation based on the National Science Foundation's track record and experience with this type of research, and on its built-in peer review process.

We also recommend that Government agencies continue to develop programs that directly support risk assessment and risk management. The efforts of the EPA and the Gulf Breeze Laboratories are an example of this type of program.

We support the expansion of such efforts, especially to laboratories with expertise in terrestrial systems. However, I would like to stress here that the risk-related research efforts of the USDA have been totally inadequate. This has been highlighted to this committee in the GAO report and discussed at length this morning.

The Committee for Responsible Genetics also support the development of large data bases that would organize and enhance our knowledge of risk assessment. These data bases should include and utilize the knowledge gained from field trials of genetically altered organisms and of environmentally released nonaltered organisms.

On behalf of the Committee for Responsible Genetics, I would like to thank you for the opportunity to share our concerns with you today.

Thank you.

[The prepared statement of Ms. Wilker follows:]

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Nachama L. Wilker
Executive Director

TESTIMONY OF NACHAMA L. WILKER
EXECUTIVE DIRECTOR
COMMITTEE FOR RESPONSIBLE GENETICS

BEFORE THE SUBCOMMITTEE ON NATURAL RESOURCES, AGRICULTURAL RESEARCH AND ENVIRONMENT AND THE SUBCOMMITTEE ON SCIENCE, RESEARCH AND TECHNOLOGY OF THE HOUSE SCIENCE AND TECHNOLOGY COMMITTEE

BIOTECHNOLOGY SCIENCE BILL OF 1986

JUNE 5, 1986

My name is Nachama Wilker, I am the Executive Director of the Committee for Responsible Genetics. The Committee for Responsible Genetics is a national non-profit organization composed of scientists, public health and public policy professionals, and others dedicated to the development of biotechnology in a safe and socially responsible manner. We appreciate the opportunity to appear before these two subcommittees to share our comments with you today on the Biotechnology Science Act of 1986.

The Committee for Responsible Genetics believes that the development of regulation for the biotechnology industry should incorporate the lessons we have learned from the development of chemical and nuclear technologies. In the case of synthetic chemicals, some of the most toxic chemicals known to humankind were brought to the market with little debate or concern for potential environmental or public health risks. Development decisions, which were heavily influenced by pressure for rapid return on investment, have left a legacy of some 60 million tons of hazardous chemical waste being produced every year.

While the promise of biotechnology can be presented as almost limitless, this potential is inevitably accompanied by some of the same types of risks associated with chemical and nuclear technologies. The risks associated with biotechnology, however have a set of significant characteristics that distinguish it from chemical and nuclear technologies. Chemical and nuclear substances do not reproduce themselves. Biological organisms have the potential to reproduce, and thus to proliferate in our environment, and to mutate further and recombine with other organisms already present in the ecosystem. From our past experience with the inadvertant introduction of organisms such as the gypsy moth and the citrus canker, we have learned how difficult it is to erradicate organisms once they have established themselves in the environment. And unlike exploding automobiles, our mistakes in this area will be very difficult to recall.

The Committee for Responsible Genetics commends the initiative of Congress to address the long-term issue of regulating the development of biotechnology. Generally, we support the bill's approach to the regulation of biotechnology through the use of a permit process, and the bill's shift of the burden of proof for safety testing for field trials of genetically altered organisms away from the agencies to the manufacturer. We also support the bill's emphasis on development of good laboratory and manufacturing practices and on the funding of new research. However, we note that these efforts require that the agencies have sufficient and knowledgeable staff with expertise in areas such as molecular genetics and ecology. We recommend that Congress ensure that agencies are provided with the necessary resources to effectively evaluate permit requests in a timely fashion.

Today we would like to address our comments to two areas of the bill: first, the community notification process in the regulation of environmental release; second, the development of fundamental research programs that support risk assessment, risk management, and large databases.

The Committee for Responsible Genetics strongly supports the development and implementation of a community notification process as discussed in the bill. Local residents are familiar with the ecology and history of their own communities. They may possess critical information that is not available to the regulating agency or the manufacturer that could bear on the results of a release of particular organisms into that community. The bill's proposed notification process, while a step in the right direction, is insufficient. Four weeks will not allow enough time for an informational exchange or proper risk communication and education in the community. Three months time would be more sufficient. And we note that a good program of risk communication would include information on how the risk assessment was conducted, as well as its limitations and force. We also recommend that in notifying local officials and planning bodies, Section 9B of the initial use permit section be amended to include notification of environmental bodies, and, where possible, local Institutional Biosafety Committees (IBC's).

The Committee for Responsible Genetics applauds the steps the bill takes toward addressing inadequacies of our existing scientific base of knowledge to deal with the questions raised by the release of genetically altered organisms into the environment. Critical questions, however, remain to be answered in the areas of risk assessment, and physical and biological containment. Our techniques for monitoring of organisms once released into the environment remain at a primitive stage in development. Fundamental research will be very important for risk assessment purposes and should be done by our most qualified scientists. We recommend this research be conducted under the auspices of the National Science Foundation, rather than the bill's recommendation of the Office of Science and Technology Policy. We make this recommendation based on the National Science Foundation's track record and experience with this type of research, and on its built in peer review process.

We also recommend that government agencies continue to develop programs that directly support risk assessment and risk management programs. The efforts of the EPA in the Gulf Breeze Laboratories - an example of this type of program - are an excellent beginning. We support the expansion of such efforts, especially to laboratories with expertise in terrestrial systems. However, I would like to stress that the risk-related research efforts of the USDA have been totally inadequate. This was highlighted in a report submitted to this subcommittee by the General Accounting Office titled, "Biotechnology: The U.S. Department of Agriculture's Biotechnology Research Efforts." This study reported that of the 87 experiments that the USDA is currently funding that are expected to involve environmental release in the next five years, only three involve any kind of risk assessment.

The Committee for Responsible Genetics also supports the development of large data bases that would organize and enhance our knowledge of risk assessment. These databases should include and utilize the knowledge gained from field trials of genetically altered organisms and of environmentally released non-altered organisms.

On behalf of the Committee for Responsible Genetics, I would like to thank you for the opportunity to share our concerns with you today. We hope that this open process will continue in the future. Thank you.

Mr. Volkmer. Thank you very much, Ms. Wilker.

I have several general questions I would like to ask members of the panel, and if you wish you may answer or not, however you so desire.

As all of you are fairly familiar with the regulations that have gone forward so far under EPA, or USDA, or NIH, to some degree, do the various Federal agencies have a clear and sufficient statutory authority to review all genetic engineered organisms intended for environment release in both research and commercial settings?

Do you want to start, Dr. Mellon?

Dr. Mellon. I guess the answer would have to be yes, in some cases and, no, in others. I think, generally, EPA has broad authority to regulate commercial releases of engineered organisms. I think the area of noncommercial nonuniversity research is an area that is totally uncovered by EPA, but I think it is the only area over which there is no jurisdiction to regulate an environmental release.

In the agriculture area, I think that they—I have testified to this to other committees—I think that the agriculture statutes are seriously deficient in the jurisdiction they give USDA to regulate releases. I might also say that the NIH regulations are limited to experiments with recombinant DNA. They do not include experiments with nuclear transplantation, recombinant RNA, or other advanced genetic techniques that appear to pose the same sort of risks as the recombinant DNA.

So I think that the answer is that there is a lot of jurisdiction, and that probably the majority of the releases that we are likely to see are covered.

The biggest deficiencies are in the agricultural area. Those statutes are deficient not only in terms of the kinds of organisms covered, but they are also deficient, as was discussed this morning, in the jurisdiction they give to EPA to regulate releases of organisms that have not been determined to be either plant pests or noxious weeds.

Mr. Volkmer. Doctor.

Dr. Hautala. The position of the ACS is that in terms of statutory authority there are certain deficiencies, which is why we have suggested that existing statutes be amended rather than that there be enacted an all-encompassing new legislation covering biotechnology. I think I outlined in my presentation the amendment to TSCA, to institute a permitting process for the release into the environment of genetically engineered organisms, and additionally of TSCA, for the institutional permits to cover noncommercial research, at research institutions. And I suggest that USDA's statutory authority be amended in a similar fashion to cover release of genetically engineered organisms and research at noncommercial institutions.

Mr. Volkmer. Thank you very much.

Mr. Gibbs.

Mr. Gibbs. Our position is that EPA and USDA have essentially broad enough authority to cover all releases that would be of significant concern. If EPA does have a gap it is a small gap, a very small gap that we feel is of minimal concern.

I am not expert on EPA regulation, but the extent of—I would defer to Dr. Moore, and Mr. Schatzow, and EPA witnesses who testified, and based on what they said, I believe that they would be correct in saying that there is essentially no gap, and the regulations that have been suggested would do a very good job of filling in whatever holes there might be.

In the USDA statute I think the authority is very broad.

I believe that the two principal statutes, the innocuous weed and the plant protection acts are very expansively drafted and would cover most problems that one is likely to see. They would affect agriculture and they would affect plants. It is not limited to agriculture but to plants and other aspects as well.

So I do believe that agriculture has sufficient authority to regulate pathogens and other substances that would enter the environment that might be of concern.

Mr. VOLKMER. Thank you, Mr. Gibbs. I would like to make one comment, though.

In your testimony you alluded to the fact that if we had had legislation as proposed here that there would have been a question as to whether we would have had interferon, whether we would have the human insulin or the human growth hormone, but this legislation that we have does not apply to FDA, and all of those are FDA approvals.

Mr. GIBBS. No; I was not speaking of the legislation now before the Congress. I was speaking of the legislation that was proposed in 1976 and 1977, that would have severely restricted research in recombinant DNA. It is a much narrower different type of legislation.

Mr. VOLKMER. Fine; you were not saying that. I wanted to clear it in regard to this legislation.

Mr. GIBBS. No; I was speaking of legislation that was proposed at the time.

Mr. VOLKMER. All right; fine.

Ms. Wilker.

Ms. WILKER. To add to Dr. Mellon's comments. The other concern that the Committee for Responsible Genetics might raise in this context is their concerns of Institutional Biosafety Committees and the role that they might play in releases in the university settings as well. Further than that the Committee for Responsible Genetics hasn't developed a more detailed position, but will be as the OSTP statement comes out.

Mr. VOLKMER. Well, as far as the utilization of Institutional Biosafety Committees, I have some reservations about doing that.

That is why, Dr. Hautala, I have some reservations about using the concept about which I have first heard, which is worth discussing, EPA, as far as those institutions that are not receiving grants, be basically approved institutionwide.

You made that suggestion.

My concern is that when we had the hearings on the vaccine for pseudo-rabies, and Dr. Kitts' operation down there—you know, I don't really know how much the Institutional Biosafety Committee, actually, how well it performed in that instance—let's put it that way. So, I have some reservations about just relying on that type of regulation.

Now, Dr. Mellon, EPA, under the new guidelines, we haven't seen them, I don't—have any of you seen the new guidelines?

Dr. **Mellon**. I have.

Mr. **Volkmer**. Have you?

Dr. Mellon, have you seen the new guidelines?

Mr. **Volkmer**. Where did you get them?

Dr. **Mellon**. In draft.

Mr. **Volkmer**. In draft?

In May, or when?

Dr. **Mellon**. May.

Mr. **Volkmer**. Prior to May 20, or subsequent to May 20, if you remember.

Dr. **Mellon**. I am not really sure. They came at night——

Mr. **Volkmer**. Pardon?

Dr. **Mellon**. They came at night, carried by a masked man.

Mr. **Volkmer**. Yours came at night, carried by a masked man; yours didn't come in a brown envelope with no return address or anything?

Dr. Hautala, have you seen them?

Dr. **Hautala**. An earlier draft.

Mr. **Volkmer**. An earlier draft.

Mr. Gibbs.

Mr. **Gibbs**. I have seen an earlier draft; we received it after May 20.

Mr. **Volkmer**. After May 20; you have seen a more recent than we have.

Mr. **Gibbs**. I am sorry, I don't know if the draft was dated after May 20, but we received it——

Mr. **Volkmer**. In other words, it may be the same.

Ms. **Wilker**. We haven't.

Mr. **Volkmer**. You are left out.

Now, under the new guidelines, should there be any comment period if there are important changes from existing policies?

Do you wish to comment on that, Dr. Mellon?

In other words, let's say they provide for exemptions of certain types of genetically engineered products that are really not going to be subject to review before release?

Ms. **Mellon**. I think that the new guidelines are quite different from the proposed guidelines that came out in 1984, and I think that a case can be made that the procedure associated with the promulgation of them, the interim finals, is deficient.

Mr. **Volkmer**. Is sufficient or deficient?

Dr. **Mellon**. Deficient.

Ms. **Wilker**. I would like to——

Mr. **Volkmer**. Anybody else like to comment?

Ms. **Wilker**. I would like to strongly support the idea of having that process open. The committee has heard some things that we have been rather disturbed about and preparing some comments when the OSTP statement is released and would strongly support the idea of having some kind of public response period.

Mr. **Volkmer**. Mr. Gibbs; Dr. Hautala; either one?

Dr. **Hautala**. I think it would be appropriate, certainly, to have a comment period on certain sections of the policy statement, perhaps on all sections. But having said that, I think it is also important that there be a procedure for having a stable regulatory environment during that comment period, particularly if that comment period should then result in redrafting of certain sections.

The instability of the environment with continual comment and revision, I think, would be very detrimental to the industry and the public at large.

Mr. **Volkmer**. In other words, they become final, but subject for review, like anything is going to be reviewed anyway?

Dr. **Hautala**. Yes.

Mr. **Volkmer**. That any comments would not hold up the finality of it?

Dr. **Mellon**. Well, there are going to be opportunities for comment in conjunction with rulemakings that are not in the package——

Mr. **Volkmer**. That will take place as a result by the individual agencies?

Dr. **Mellon**. Yes; so I think there will be opportunities to raise the issues.

Mr. **Volkmer**. Mr. Gibbs.

Mr. **Gibbs**. The comments—when the proposal was first issued in December 31, 1984, the agencies received a number of comments, and many of the changes have been made in response to the comments. What sometimes happens with any kind of administrative rulemaking procedure is that the final rule will be somewhat different, or substantially different from the original proposal.

But as long as the final rule reflects the comments, and is predicted on the comments, and made in response to the comments, the courts have that it complies with the administrative procedure act. The problem if you don't have that kind of rule is you keep going through an endless cycle of rulemaking where people—you have proposal, comments, a final rule, and it goes on and on.

I would believe here that as a matter of law there may not be a need for additional rulemaking. I would recommend, and ABC, would certainly like to have the change to issue comments, not in the context of formal notice and comment rulemaking, which would be subject to revision, because as we have just heard there would be a difficulty and the instability that would result.

But I believe that the rule should be final except for those parts which are still open for notice and comment rulemaking, and the record should remain open for additional comments.

Mr. **Volkmer**. Dr. Mellon, is there a reason to believe that organisms taken from a nonpathogenic base, which are modified by gene deletion techniques only, pose no risks to the environment or public health, and can be released into the environment without any prior regulatory review?

Dr. **Mellon**. I believe that there is evidence to demonstrate that that is not the case. At the ASM meeting held in Phildelphia, in June of last year, there was a report on an instance of a single gene deletion that resulted in the loss of an inhibitor and the manifestation of an increase in host range of virulent plant pathogen.

Mr. **Volkmer**. OK. Is there reason to believe that intergeneric micro-organisms which contain only additions of on coding regulatory sequences pose no environmental risks?

Dr. **Mellon**. I addressed that in my comments. I think the answer is probably, "No"; because I think that these regulatory sequences operators, promoters and terminators they are the turn-on and turn-off signals in the genetic code.

It seems to me that you can certainly think of cases in which the transfer of a promoter into an organism would not have much of an effect, it just might increase the rate at which the gene was transcribed, but you can also think of cases in which tinkering with the turning on and turning off signals could produce very significant effects.

You could turn on, for example, fetal genes in adult organisms or vice versa, you might be able to turn on batteries of genes together that haven't been turned on before. In each of these instances, I think, you would approach a degree of novelty arguably, like that you would find in an intergeneric cross.

Mr. **Volkmer**. You all have addressed parts of the legislation and discussed and appreciate that. There is one thing that we have found through our hearings, that we find some dispute, and that is what is a release? Anybody want to comment and help us out on that; or if you don't, just—no one?

Ms. **Wilker**. The committee is in the process of developing what we consider to be a definition of a "release."

Mr. **Volkmer**. Would you be so kind that when you have completed that to send it to us?

Ms. **Wilker**. Yes.

Mr. **Volkmer**. We are open to all kinds of suggestions; we will look at them all; reject what we don't like; and take what we like. I would like to have suggestions because we are still looking at it.

Dr. **Mellon**. I wish you luck.

Mr. **Volkmer**. Will you agree on one thing though, that it is necessary in order to have a regulatory process so that anyone that is in the field, working on this genetic engineering, should know what a release is; and that we don't have disputes on what a release is?

Dr. **Mellon**. Essential; it must be defined, and it must be defined in a——

Mr. **Volkmer**. I agree it is not going to be easy, but that shouldn't stop us.

I have no further questions.

I want to thank this panel and the previous witnesses for their testimony, it has been very helpful.

In closing I would like to say that I along with, I think, many others here await anxiously the final guidelines. When that happens we will probably be back, going at it again.

Thank you very much, I appreciate your being here today.

That will conclude the hearing.

[Whereupon, at 4:10 p.m., the hearing concluded.]

APPENDIXES

Appendix I

Testimony of

Thomas P. Grumbly
Executive Director

The Health Effects Institute

before

The Subcommittee on Natural Resources,
Agricultural Research and the Environment

The Subcommittee on Science, Research and Technology

Committee on Science and Technology

House of Representatives

June 4, 1986

My name is Thomas Grumbly, and I am testifying today in my capacity as Executive Director of the Health Effects Institute. I appreciate the opportunity to testify on the relevance of the Health Effects Institute to the Biotechnology Science Research Program proposed in H.R. 4452.

The Health Effects Institute is an important new step in the conduct of the environmental science that must underlie public regulation, one that I believe to be enthusiastically supported by the leadership of the Environmental Protection Agency and the managements of those industrial companies that make and market motor vehicles or their engines in the United States. The Institute is a unique way of bringing government and an industry together to tap, under independent auspices, the best scientific talent available at our universities and research institutes and so to provide the kind of scientific base for government regulations in which the public can have confidence - here the regulation necessary to safeguard the public health from any dangerous emissions from motor vehicles. We believe that HEI is a model for joint government - industry cooperation in attacking mixed problems of science and regulation in other fields. In our remarks today, we will describe (1) the genesis of the Institute, (2) the current governance structure and funding, (3) the broad outlines of the scientific program, and (4) some other areas including biotechnology in which the HEI model might be useful, (5) and some lessons in "founding" that could guide you in forming any new joint ventures.

1. The Genesis of HEI

I can describe the origins of HEI best by explaining how the founders, Archibald Cox, Donald Kennedy, and William Baker came to be interested. As men widely experienced in the conduct of government policy affairs and science policy in and on the fringes of government, they knew that proposals for government regulation of industry to protect the public health and safety, all too often produced bitter disputes about the knowledge of scientific data conclusions at their base. Leaving the search for knowledge concerning the health effects of possibly harmful substances to the adversarial process engaged precommitted experts on each side as each attempted to use science to advance its interests. The process not only wastes scarce resources, but also subverts the purposes of science and obscures the real social policy differences that ought to be thoroughly debated. Often the best scientists simply refuse to participate. Still worse, total resort to the adversarial process obscures the fact that government agencies and the industry share common interests and responsibilities that they should join in recognizing - common interests and responsibilities not only in good science but in the public health.

Consequently, these gentlemen were greatly interested when invited by then EPA Administrator Douglas Costle, and encouraged by William Ruckelshaus, when he was in the private sector, to serve as Directors of the new organization -- now the Health Effects Institute - that EPA and the motor vehicle manufacturers were hoping to work out, dedicated to quality science in regulation and to building bridges between the public and private sectors. All of them, and the others involved in the foundation, thought it essential that this new Institute be built in such a way that it would be truly independent and thus credible and accountable to the public.

II. The Unique HEI Governance and Funding Structure

To achieve, there had to be agreement upon four points. HEI's principal governance and funding structures grew from them:

o HEI must be truly independent in governance - free to make its own decisions in developing not only the general program of research but the specific grants and protocols. In order to ensure relevance to potential regulatory needs, HEI would regularly consult the sponsors and other interested groups, such as environmental organizations; but it would then make its own decisions. Similarly, findings would be published without prior clearance by either industry or government.

o HEI must have financial support from both government and industry, so that both government and industry would have a stake in the venture, so that we would have incentive to listen to both but bow to neither, and so that the public could have confidence o HEI must be dedicated to quality science from definition through review: The new institution must be structured to define, select, support, and review research to promote the application of the best science to the possible effects of mobile source emissions.

Senior management in both government and industry took the challenges seriously and gave assurances upon these points. Funding is provided on a fifty-fifty basis by the Environmental Protection Agency and twenty-five manufacturers of cars, trucks, and engines who market in the United States. The manufacturers and the EPA under successive administrators have committed themselves to the belief that they can rely upon HEI as the major source of studies on the health effects of motor vehicle emissions in this country. At present, the Institute has a budget of about 6.5 million dollars annually, and it accounts for nearly half of all the research done on these issues in the industrialized world, including Japan and Europe.

Before discussing the HEI scientific program and the possibilities for "cloning" this form of organization in other areas such as biotechnology, however, I want to emphasize the benefits of this mode of programming regulatory research. It has the obvious benefit of reducing the overall amount of money that must be spent by society on research. Not only does the taxpayer receive two dollars of research for every federal dollar expended, but the money is not spent in an adversarial fashion with unnecessary duplication and in attempts to undermine the factual base. No longer do we have government research programs that industry suspects are aimed at justifying regulations and industrial research programs applying more money in a defensive fashion. Scientists participate who would not work for government or industry alone. We also are developing a common fact base upon which policy decisions can be debated. The joint and equal funding of the Institution, as well as its mode of governance, enhances the probability of public acceptance of the science because there are no incentives for systematic bias. Ultimately, the program has to meet the true needs of both the public and the private sectors; if we satisfy only one or neither, we will fail and will cease to exist. Our funding and governance structure, therefore, creates a controlling incentive to engage the very best scientific resources, to call the shots solely as we see them, but to do so in an accountable way.

III. The HEI Scientific Program

Mr. Chairman, HEI actually has been sponsoring research only since the summer of 1983. The prior time was spent in a very careful effort to put together the best possible scientific panels, to develop a scientific funding process that would earn scientific and public confidence, and to recruit a small but outstanding scientific staff.

HEI currently has about 50 studies underway with principal investigators at 35 research institutions in the United States. It also sponsors, with its industrial funds, several studies at institutions in West Germany, Canada, and the United Kingdom. These studies are oriented toward providing the scientific underpinning necessary for rational decisionmaking with respect to the National Ambient Air Quality pollutants, Nitrogen Dioxide, Ozone, Carbon Monoxide, and Diesel Particulate. The Institute is also sponsoring studies to ensure that future technology does not pose unreasonable risks to the public health. In particular, the Institute is investigating the effects that new fuel mixtures might have on levels of pollutants such as formaldehyde.

HEI's Research Committee, a distinguished group of scientists chaired by the current foreign secretary of the National Academy of Sciences and former provost of MIT, Walter Rosenblith, prepares the research program for submission to the Board of Directors and supervises the award of contracts for specific research. The Committee entered the air pollution problem in midcourse, after our society had more than a decade of experience with living under the demands of the Clean Air Act. In setting the original National Ambient Air Quality Standards, the Congress had necessarily made policy judgments regarding standards, sometimes in the absence of a well-developed scientific base. In tackling a highly contentious area of science, our Research Committee recommended, and the Board agreed, that we try to do research in a way that increased our understanding of what was happening as emissions left the tailpipe, interacted with the atmosphere, entered the human pathways, and finally reached the human organs of particular concern. In response to this rough flow diagram, and to the inherent problems of all modes of research in the environmental sciences (whether they be animal toxicology, in vitro studies, epidemiology or human clinical experiments), the Institute has shaped a program that attempts to build both a broad scientific base, as well as to address near-term regulatory problems. Indeed, it is, in part, in the attempt to merge regulatory relevance with the development of an up-to-date scientific base that we hope to show that HEI is different.

To implement a strategy of combining new principles with old problems, HEI has chosen to use the scientific equivalent of the "free market". We define problems that are of both regulatory and scientific importance, and then leave it to the research community to respond in a competitive fashion by making specific, detailed proposals for research projects. We carefully review the applications with respect to both scientific merit and regulatory relevance and fund about 15% of the applications we receive. Through this process, we have been able to attract a number of first-class investigators into this area who did not work in it before.

Our current work is exemplified by a number of different projects, immediately relevant to regulation, including:

o A multi-center study of the health effects of low levels of carbon monoxide on patients with heart disease. This set of studies is being conducted in response to a major problem encountered by the government in interpreting prior studies, some of which may have been fraudulent. The current HEI study will be directly relevant to the next standard-setting process for CO.

o A set of studies on Nitrogen Dioxide, conducted in different clinical settings, on different kinds of patient populations, to determine whether particular susceptible populations exist. This determination of susceptibility is important because of the requirements of the Clean Air Act to set standards to protect sensitive populations.

o A set of wide-ranging studies on the health effects of diesel particulates. Taken together with animal toxicology that was commissioned around the world before HEI was established; this work may have a significant effect on future EPA regulation.

o An evaluation of the health effects of gasoline vapors, conducted in order to assist EPA and the industry in clarifying the uncertainties in the existing data base.

A unique element of HEI is embodied in its scientific evaluation function. Once research is completed, it is subjected to an intensive peer review by the Institute's Review Committee, which had no role in selecting, shaping, or monitoring the project. This Committee, which is chaired by Dr. Robert Levy, Professor of Medicine at Columbia University and former Director of the National Heart, Lung and Blood Institute, develops a technical evaluation of the project, which is published along with the scientific report of the investigator and a message from the Board of Directors. The report is designed to clarify findings, particularly for the non-scientific decision maker, and to provide a comparative assessment among research projects in a particular area.

I would now like to discuss briefly some of the broader ramifications of the HEI model, and lay out some of the lessons we have learned and urge you to consider as you move forward.

IV. Evaluating Success and New Problems

We believe that it is still too early to say definitively whether HEI is a success, but the signs are promising. No one questions the independence and integrity of the organization, nor is there any quarrel with the quality of the science. We have already encountered an issue -- gasoline vapors -- in which a report of the Institute tended to question the strongly held beliefs of some members of the sponsor community. In that environment, we have managed to maintain the support of all of the sponsors, particularly at the senior management level. Our program is responsive to sponsor needs, while maintaining an independent understanding of what good science demands. Perhaps most importantly, we have demonstrated the possibility of developing a community of interest among scientists and non-scientists, where previously animosity predominated.

To be sure, there are still and will continue to be tensions -- mostly constructive -- in finding a working definition of "relevance" that scientists, and those concerned with near term decisions, agree to and are comfortable with. And there are still people, in all sectors of our society, who find it in their interest to continue battles, rather than to find ways to ameliorate conflict.

Given this overall picture, we believe that several problems, including the risk of genetically engineered organisms, would be amenable to the HEI model.

o Risk Assessment and Biotechnology: The Problem of Deliberate Release

As new technology emerges from the commercial laboratories of the country, it is clear that the typical industrial context needs to be enlarged in order to ensure public confidence. The government has been struggling to try to develop an appropriate regulatory stance, in the absence of very good scientific guidelines. It would seem extraordinarily useful to merge public and private resources under a credible umbrella to spend time on general issues of hazard identification and exposure in this very uncertain area.

In looking at the HEI model for the biotechnology problem as I currently understand it, it is important to recognize the kinds of problems it can and cannot effectively work on. A joint venture can be most useful to explore some of the fundamental biological problems inherent in hazard identification, to evaluate dispassionately work that other people have already published and invested substantial resources in, and in translating science -- both its own and others -- to non-scientific decisionmakers. This "translation" process does not mean that the Biotechnology Science Research Program would attempt to propose policy solutions; rather, it would attempt to demonstrate how new research fits into an overall body of science in narrowing the uncertainties about risk.

HEI was made much more effective by the inclusion of a provision in the 1977 amendments to the Clean Air Act that forced manufacturers to certify to EPA that new technology would not pose an "unreasonable risk" to the public health. HEI has developed a role in helping manufacturers work on generic health effects issues and in using the data that is generated in an independent, credible fashion. HEI does not "certify"; the manufacturers still bear that responsibility. However, the presence of such a provision provided a statutory "driver" that provided great incentive for industrial participation.

An organization like HEI is not useful in working on problems that have direct trade secret consequences. The necessity for openness and wideranging scientific discussion makes it highly unlikely that very specific technologies can be explored through a joint venture. An example from the automotive community perhaps can make this clear. HEI has been effective in helping evaluate whether manganese per se should be used as a regenerator for diesel particulate traps. It has not been useful, however, in describing whether any particular trap, one that may produce a strange species of manganese, presents problems. This latter information can really only be described by the manufacturer,although HEI can provide some help in suggesting what problems to look for.

In addition to the Biotechnology area, it is possible to see the HEI model being effective in other areas, including:

o Problems of indoor air pollution

Evidence continues to mount that air pollution is a problem indoors (for example, in residences, schools, offices, commerical and public buildings) as well as out. Studies have documented an indoor buildup of toxic and carcinogenic emissions from passive tobacco smoke, unvented gas-fired appliances, building materials, furnishings, consumer products, and underlying soil. The relative risks of indoor, as opposed to out-door, air pollution for individuals and populations are not well defined. Yet, adverse health consequences from indoor exposures are a potentially serious public health problem of enormous dimensions. This emerging environmental health issue offers an opportunity for industry-government cooperation to define the extent and magnitude of the problem, and to design appropriate control strategies. Application of the HEI concept to indoor air quality issues appears to be a logical and natural outgrowth of HEI's mission.

o The Risks of Toxic Air Pollutants

The fear generated by both the Bhopal situation and the Institute, West Virginia leak emphasizes again the necessity for a credible scientific institution that can systematically evaluate the risks of many chemicals. We believe that an organization like HEI could make a major impact on the chemical evaluation problem.

Every policy problem presents its own particular set of dynamics. Among the many lessons we learned in the establishment of HEI is that cooperation is not easy. Substantial efforts must be made to provide the resources and the organizational catalysts that will be necessary to stimulate these kinds of public-private-university organizations. It is, however, possible to succeed, if the right group of people is attracted to a credible and independent institution. Success is also only possible in an environment in which the government itself has a strong scientific program. Organizations like HEI can most effectively complement the internal research apparatus of regulatory agencies; they should not simply supplant them. The government must continue to have or develop its own cadre of skilled scientists to interact with the broader scientific community, to perform and evaluate work in short-term time frames, and to provide sound advice on a daily basis to decisionmakers.

V. The Lessons of Cooperation

In its foundation, HEI encountered major problems and learned several lessons, which can be summarized briefly:

o Major conceptual difficulties are involved in redefining problems so that non-traditional solutions are possible. Adversarial roles must be put aside; existing institutions must be persuaded to suspend disbelief about the possibility of building trust. In short, substantial efforts must be made to change people's existing worldviews views about the possibilities of change.

o Any new organizations should be personified first through visible leadership before prospective partners will take them seriously. In HEI's case, it was critical to have someone of the stature of Archibald Cox as Chairman, as well as the President of Stanford University, Donald Kennedy, and William Baker, the Chairman of Bell Laboratories, as board members before all of the organizational details were worked out. Detailed structure followed from personal commitment. In some respects, this is counter-intuitive and even contrary to traditional organizational theory.

o It is necessary that organizations in addition to the Federal government be seen to be in the lead; the mistrust of government in wide areas of academia and business is such that business or foundations must also make an initial effort if joint ventures are to succeed.

o New efforts may face major obstacles from existing organizations within the government, private sector, and trade associations. Some people will attempt to paint potential new actors as too "academic", too slow, too unresponsive, etc. This will be a continuing, and not always productive, struggle which is simply a fact of organizational life. Accordingly, the Congress will have to be willing to be patient while these often self-serving cries of pain subside.

o It is possible to attract first rate scientific talent in cooperative research programs, and in areas of great prior conflict, but only in an environment in which independence is essentially guaranteed, not only in words, but in the incentive system of the institution. Independence requires not only a strong Board of Directors, but also a financial situation in which those working in an organization have a strong incentive to behave independently. Thus, the funding of cooperative institutions must be balanced in terms of all interested parties, such that withdrawal of one sector of support would jeopardize the survival of the institution.

o This requirement for independence probably means that only certain types of situations will be amenable to cooperative scientific work. Among these are:

-- Areas in which partners have no previous positions, and consequently are not locked into defensive stances. In this case, corporate and governmental partners can mutually explore a situation without worrying about past positions.

-- Areas in which conventional solutions have been exhausted and in which the level of tension is still quite high.

-- Areas in which the economic stakes are sufficiently high so that failure to resolve problems is quite costly to private industry and politically unacceptable to the government.

The personnel currently involved in the organizational structure of HEI have been remarkably cohesive over the past five years. Consequently, there is a wellspring of knowledge at the staff, scientific, and policy leadership levels that can be applied to other problems, in order to make new relationships grow. No one expects that every problem will be exactly the same as, or even similar to, the policy problem encountered in building the Health Effects Institute. However, HEI has been an ideal proving ground for many concepts, many problems have been met and overcome, and the personnel associated with HEI have the personal and organizational experience and skills to overcome similar problems in other ventures. I think, therefore, that it would be advisable for HEI to be involved in the development of new cooperative efforts.

VI. The Importance of the HEI Experiment

In closing, Mr. Chairman, I want to emphasize again the importance of the HEI experiment in the context of overall research and development policy in the 1980's. A period of very tight resources looms in front of us, as we struggle with the budget. In the Health Effects Institute, we are testing a model that has wide applicability both within and without regulatory science. If our nation's scientific and technological base is to continue to fuel our economy, we must find ways for industry and government to collaborate effectively and to pool research resources. Many people talk about industrial-governmental collaboration: the EPA, the automobile industry, and a major piece of the scientific community are doing something about it. The concept behind HEI, and the institution itself, deserve the Federal government's support, in FY 1987 and beyond.

With your permission, Mr. Chairman, we are attaching a copy of the HEI bylaws to our testimony, so that the Committees can see how we are currently structured, as well as a copy of our most recent Annual Report, which contains detailed scientific and financial information about the Institute.

Thank you for your attention.

APPENDIX II

AG-303 REV. 11-84

DU PONT
ESTABLISHED 1802
E. I. DU PONT DE NEMOURS & COMPANY
INCORPORATED
WALKER'S MILL, BARLEY MILL PLAZA
WILMINGTON, DELAWARE 19898

AGRICULTURAL CHEMICALS DEPARTMENT

July 9, 1986

U.S. House of Representatives
Subcommittee on Natural Resources
388 House Office Building Annex #2
Washington, D.C. 20515

Gentlemen:

In response to the request of the subcommittees for a statement of Du Pont's views on H.R. 4452, we are in general agreement with the testimony recently delivered by the Industrial Biotechnology Association on H.R. 4452 and also offer the following for the record.

Our approach to research, development and commercialization of biotechnology has been to support the development of the NIH guidelines and the development of good laboratory practices for R&D. Our policy is to follow the requirements of the NIH-RAC guidelines. When public debate focused on whether or not the procedures in place were adequate to review the safety, health and environmental impacts of new biotechnology products, we reviewed the existing statutory framework and concluded that existing laws gave the various regulatory agencies the authority needed to assure that safety, health and environmental concerns would be addressed. Therefore, we urged each responsible government agency to develop a regulatory regime appropriate to the products that came under its jurisdiction. We believe that the various agencies took an important step in this regard on June 26, 1986, by publishing their final policy statements on the regulation of biotechnology. Although further regulations will be developed and adjustments will be made, we believe that the various agencies' programs present a valid approach to regulation of biotechnology.

We recognize the need for federal review of field testing and commercialization of biotechnology products and

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believe that such oversight can be accomplished effectively without the need for additional legislation. The June 26 publication of the policies of the various agencies for the regulation of the products of biotechnology supports our conclusion. We are pleased that the various agencies are coordinating the science base that will be used by each regulatory agency. The Office of Science and Technology Policy has established a Biotechnology Science and Coordinating Committee (BSCC). We believe that the approach adopted is a sound one that will ensure that good and consistent science is employed by the various agencies as the basis for regulation. We believe that the committee as established on October 31, 1985 will accomplish this goal. Thus, there does not appear to be a need for this provision in new legislation.

We have been asked to present our views on the proposed Biotechnology Science Research Program. H.R. 4452 would establish a Biotechnology Science Research Program (BSRP) to develop a data base to support the review and regulation of the biotechnology sciences and to identify areas of research that will facilitate the development as well as the regulation of biotechnology. We agree that such a program would be beneficial. We presume that in practice the BSCC would coordinate with other independent organizations such as the National Academy of Sciences and universities to avoid duplication of effort, develop complementary programs, and bring together in one data base all ongoing risk assessment research and the results of all completed research relevant to the mission of the BSRP. We doubt that this program would move forward promptly if the requirement is retained that a majority of the funding comes from the private sector. If legislation to institute a BSRP is adopted, we recommend that this requirement for a specified level of private sector support be removed. The biotechnology industry is one that shows great promise, but is also one that does not generate substantial current revenue. Moreover, the United States is in a race with other nations to turn the promise of biotechnology into a profitable industry. To maintain world leadership of our industrial biotechnology companies, we must avoid duplication of effort to develop good risk assessment techniques. Development of the proposed BSRP data base would be an effort which could avoid such duplication.

The subcommittees asked for our view of the definition of genetically engineered organism as set out in H.R. 4452. Genetically engineered organism is defined as organisms that have been deliberately altered to contain genetic material derived from more than one taxonomic genus. We do not believe that including only those engineered organisms derived from more than one taxonomic genus is adequate. As discussed in the June 26, 1986, Federal Register notice, regulated organisms include certain intergeneric combinations and intrageneric combinations such as organisms derived from pathogens. The approach adopted by the federal agencies under the direction of OSTP appears to us to be more appropriate for regulating the products of biotechnology than is presented in the bill.

If the subcommittees decide to move forward with this bill, we would encourage them to consider seriously the definitions developed by the administrative agencies and presented in the above Federal Register notice.

The subcommittees asked for our comments on whether or not organisms derived through recombinant DNA techniques be subjected to federal permitting authority only when such organisms are released into the environment. H.R. 4452 provides for permits under three circumstances: intentional release of a genetically engineered organism into the environment, use of a genetically engineered organism in manufacturing, and distribution in commerce of a genetically engineered organism intended for release into the environment or for use in manufacturing.

We believe that Government oversight of each of the above activities is appropriate. We also believe that the type of oversight specified by the various federal agencies in the June 26, 1986, Federal Register notice is preferable to an across-the-board permitting scheme. That is, for some applications a permit or license will be required, while for other applications, the agency will be given advance notice of the intended use of the genetically engineered organism and can intervene if it appears the proposed action will pose a risk. We believe that the system adopted by the various agencies recognizes the relative potential risks and allocates government resources to those applications that warrant them. We also believe that the multitiered permitting scheme set out in H.R. 4452 would be unduly burdensome to both the agencies and the biotechnology industry. Such a multitiered scheme would be both a cost and a time disincentive to domestic commercialization of biotechnology.

In response to the question concerning the need for a requirement for liability insurance or other assurance of financial responsibility similar to the requirement under the Resource Conservation and Recovery Act (RCRA), we do not believe that separate insurance limited to a company's biotechnology efforts is needed or desirable. Singling out companies engaged in research and development related to biotechnology could prove to be a significant barrier to small companies which could not satisfy a RCRA-type financial responsibility test and which would be required to obtain insurance in today's difficult insurance market. As the subcommittees are aware, the number of insurance companies writing RCRA insurance is declining and many companies now need to rely on satisfying the financial responsibility test. We believe that the issues surrounding liability insurance affect all aspects of public and private sector operations and should be dealt with comprehensively rather than in a piecemeal manner.

The subcommittees have also asked whether or not federal agencies should continue to review all organisms intended for environmental release on a case-by-case basis just as NIH-RAC has done in the past. We believe that conducting such reviews in large measure on a case-by-case basis with a view toward the development of general criteria for future reviews is a responsible approach. The agencies are, however, developing guidelines as to the type of information that should be submitted to facilitate review. As with any evolving science, the agencies are adopting a conservative approach to information requirements and we anticipate that these requirements will be modified as experience is gained in reviewing the products of genetic engineering.

Lastly, you ask whether existing statutes provide sufficient authority for agencies to collect data and to conduct appropriate pre-release review of genetically engineered organisms. We believe that the agencies have ample authority under existing laws to conduct pre-release reviews of genetically engineered organisms. We also agree with the approach, as published in the June 26 Federal Register, to have each agency review the products of biotechnology in their respective areas of expertise. Thus, we do not agree with H.R. 4452's approach of removing the jurisdiction over genetically engineered microbial pesticide releases from the Office of Pesticide Programs. We also believe that it is unwise to statutorily mandate the multitiered permit system as is set out in H.R. 4452. We agree with the approach taken by EPA which will involve review of all intentional environmental releases of genetically engineered microorganisms within the Agency's jurisdiction.

In summary, it is our view that the actions taken by the various federal agencies on June 26, 1986 are appropriate and there does not appear to be a need for further legislation at this time.

Very truly yours,

Edward W. Raleigh

Edward W. Raleigh

EWR/GAH/1/paa
COMSCITEC

APPENDIX III

CALGENE

July 14, 1986

James H. Scheuer
U.S. House of Representatives
Subcommittee on National Resources
388 House Office Building Annex #2
Washington, DC 20515

Dear Congressman Scheuer:

We appreciate the opportunity to comment on HR 4452. This opportunity is timely in light of the publication of the OSTP policy in the June 26 Federal Register.

We see two major problems with HR 4452, one common to the OSTP policy, and one specific to HR 4452. In addition, we see no compelling argument that new legislation is needed at this time, given the recency and comprehensiveness of the OSTP policy.

The problem common to HR 4452 and the OSTP policy is the definition of intergeneric organism. This problem is by no means a trivial one, since the definition determines to a large extent whether or not a genetically modified organism is regulated. Many organisms used in crop agriculture today fall under the definition of intergeneric organism used in the OSTP policy and HR 4452. Transfer of genetic information from other genera to our crop plants (a good example is wheat) can be accomplished by means other than recombinant DNA. I believe it is fundamentally unsound to define what is to be regulated in this way. The definition should be based on the characteristics of the organisms to be regulated, not the means by which the organisms are obtained.

The problem specific to HR 4452 is Title IV, Section (d)(9), which outlines public disclosure requirements. Since these disclosures would not increase the safety of deliberate releases in and of themselves, requiring them is contrary to the intent of HR 4452, that intent being to ensure that adequate regulatory mechanisms are in place. Our position is that it is the applicant's responsibility to ensure public acceptance, and that the means of achieving this acceptance should be at the applicant's discretion.

In closing may I say that, on behalf of my colleagues at Calgene, we welcome the progress that has been made in the past year in defining the issues and clarifying the mechanisms for regulation at the Federal level of biotechnology for field use. We question, however, whether in light of OSTP policies recently announced there is a need for new legislation. If I may be of any further assistance, please do not hesitate to call on me.

With best regards.

Yours sincerely,

Robert M. Goodman,
Vice President
Research & Development

RMG:ds

cc: L. Kunimoto
R. Salquist

bcc: A. Goldhammer, IBA
B. Sway, CSIBA
R. Nicholas

APPENDIX IV

GRACE

F. Peter Boer, President
Research Division

W. R. Grace & Co.
7379 Route 32
Columbia, Maryland 21044

(301) 531-4428

June 30, 1986

Subcommittee on Natural Resources
388 House Office Building Annex #2
Washington, DC 20515

Gentlemen:

H.R. 4552, a Biotechnology Science Coordination Act, has several worthwhile objectives. These include the development of a coordinated and predictable Federal policy which would (1) remove the uncertainties in the present regulatory process, (2) improve public confidence in biotechnology and the process by which it is regulated, and (3) retain American leadership at the forefront of this technology. We are in agreement with these objectives. It would appear to us, however, that the second and the third objectives will not be met by the bill.

We are of the belief that the benefits of biotechnology will vastly outweigh the risks, and that a process which significantly impedes the development of this technology will be a disservice to society. A major concern to us is that the benefits to human health, welfare, and the environment potentially achievable through genetic engineering technology are not considered or weighed in the bill. The tone and language imply that there are mainly risks associated with genetic engineering. The last 15 years of experience suggest that at least some of these risks have been substantially exaggerated, and many of the others are based on little more than speculation. Excessive emphasis on risk can only lead to increased public concern about genetic engineering and a chilling effect on innovative research in the field.

We are, of course, supportive of current and future legislation which provides or will provide safeguards against unreasonable risks.

The series of three Use Permits in the proposed legislation will put U.S. companies at a competitive disadvantage in developing products using genetically engineered organisms. As written, Use Permits are required for organisms not intended for release, and for those considered for "manufacturing on an experimental basis." This is a very broad restriction which could require permits for all pilot scale experimentation. I would estimate that more than half of W. R. Grace's current R&D efforts in biotechnology might require such permits.

The decision to seek a Federal permit for experimentation will be inevitably viewed as a major go/no go point by research directors owing to the costs, uncertainties, and delays involved. Small projects and projects with still unproven financial rewards will be eliminated at or before this checkpoint.

The limited three-year duration of the Commercial Use Permit will also be a negative factor in a business decision as to whether to commercialize a new product concept based on genetic engineering technology.

It has been estimated that the cost to develop a new pharmaceutical has reached $90 million, and a new pesticide approximately $50 million. These costs, largely imposed by the regulatory process, have restricted commercialization of new products primarily to firms with very substantial resources, and have crowded out entrepreneurial activities. In addition to limiting research to large firms with great resources, another consequence of regulation has been to stifle research in areas which do not address substantial markets. As a result, new products for the less common diseases and smaller crops are considered uneconomic targets by sophisticated businessmen. It is not our purpose here to discuss whether these existing regulations are, taken as a whole, beneficial or detrimental to society, but to point out that the decision to impose potentially large financial hurdles on the young biotechnology industry should be taken with caution.

This legislation is clearly flawed in its definition of a genetically engineered organism. The definition used would seem to include many hybrid organisms not constructed by genetic engineering that have existed without concern in the environment, such as the beefalo. Yet, this definition would not include the ice-minus bacteria that have been at the center of recent controversy. A workable definition that facilitates discussion of the more significant potential risks would appear to be a key element in a successful bill. We do not believe that such a definition would be easy to write, and feel this subject deserves more study.

In summary, it is our view that the public safety is adequately served by existing regulations. While industry faces significant uncertainty in the current regulatory environment, coordinating activities are already taking place to improve the situation. We do agree there is room to improve the laws regulating and coordinating the activities of the biotechnology industry, and that both industry and the public can be well served by such improvements. Further experience with genetic engineering technology can only improve our understanding of what types of rules will ultimately best serve the interest of public safety and public benefit. We fear public confidence may not be improved by new legislation--indeed the very fact of such legislation and the creation of a new governmental committee may lead to apparent validation and perpetuation of concern over hypothetical risks. The proposed legislation appears to us, on balance, not to improve the situation, and it may prove premature to attempt to write a comprehensive regulatory program for biotechnology.

Sincerely,

Peter Boer

F. Peter Boer
President
Research Division
W. R. Grace & Co.

Vincent F. Simmon
Vice President
Biotechnology Research
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Appendix V

OSU
Oklahoma State University
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July 18, 1986

The Honorable Don Fuqua
U.S. House of Representatives
2269 Rayburn House Office Building
Washington, DC 20515

Dear Congressman Fuqua:

The Division of Agriculture Committee on Biotechnology of the National Association of State Universities and Land-Grant Colleges has reviewed H.R. 4452, the Biotechnology Science Coordination Act of 1986, and your accompanying comments. This bill is of special interest to our Committee in that it relates directly to issues we have been addressing for the past several years in the context of existing laws and administrative framework. Our committee was organized in 1982 to study policy concerning biotechnology research and educational activities, industry support of biotechnological research in agriculture in land-grant institutions, and other related matters. Committee memberships includes individuals with varying degrees of administrative responsibility for agricultural research, education, and extension programs in land-grant institutions and an attorney versed in legal and regulatory issues in biotechnology and agriculture.

We appreciate your support of genetic engineering and related research and your concern for safe and timely progress of the biotechnology industry. We share your belief in the promises biotechnology offers to agriculture, medicine, hazardous waste treatment, and other fields. Public confidence in the safety of these new techniques has also been a major concern of this Committee. However, the Committee on Biotechnology does not feel that experimentation for research purposes should be subject to rigorous regulation in the form of federal permits. Still, the novelty and unique quality of modern biotechnology necessitate special care and oversight.

We feel that any new oversight should recognize (1) the success of the National Institutes of Health Recombinant DNA Advisory Committee (NIH RAC), (2) the existing base of research data in related areas, especially regarding environmental releases of agricultural products, and (3) the regulatory controls which exist for the dispersal of products into the stream of

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AND TECHNOLOGY

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commerce. No one should question the success of NIH RAC's operation under the "Guidelines for Research Involving Recombinant DNA Molecules." This system has succeeded, not through regulations and permits, but through voluntary participation by the scientific community. Its network of Institutional Biosafety Committees (IBCs) has utilized appropriate scientific expertise and has achieved efficacy and efficiency throughout the country at the institutional/local level. IBCs communicate needs to the national level through NIH RAC, and when appropriate, review is undertaken by NIH RAC. The NIH RAC system is open to public scrutiny and has the advantage of input from various federal agencies.

Agricultural interests have been represented in NIH RAC since its inception. When appropriate, the agricultural expertise and research base within the United States Department of Agriculture has been utilized in decisions of NIH RAC. As new questions are posed by advances in biotechnology which involve releases of organisms into the environment, this history of careful review and cooperation should be employed to find proper answers. The new regulatory framework that would be established by H.R. 4452 would not seem to take full advantage of existing structures and institutions which house the expertise to evaluate properly the scientific issues involved in releasing genetically engineered organisms into the environment. The NIH RAC process has worked well, and we are fortunate to have that system upon which to shape oversight of experimental releases of genetically engineered organisms.

Agricultural research in the United States is linked together by a national system of Land-Grant Colleges and State Universities. Interactions also exist with private universities and research institutions. These relationships can be expanded easily to meet national and international needs in biotechnology. Our Committee has proposed that the Department of Agriculture tap this vast pool of resources to promote safe advances in agricultural biotechnological techniques, to insure public confidence in Recombinant DNA technology, and to provide a healthy research base upon which this nation can structure a sound industry in biotechnology. This will help our country achieve the enormous potential of biotechnology for broad social benefit. This program is called the National Biological Impact Assessment Program, and the concept is being implemented by the Assistant Secretary for Agriculture for Science and Education as outlined in the recently published policy statement and Guidelines for Biotechnology Research of USDA.

The implementation of the "Biotechnology Science Coordination Act of 1986" could unnecessarily retard important research and needlessly compound regulatory hurdles for industry. Scientists have proceeded cautiously throughout the development of Recombinant DNA and other new biotechnological processes because of the new questions that are presented. It seems overly restrictive to implement permit regulations on scientific processes that do not present demonstrated or identified dangers and do not involve distribution in commerce. Regulations are in place which protect the public from dangers or risks of products in interstate commerce. If a product is dangerous, it is not relevant by what process it was created; regulation is appropriate. There has been no demonstration that genetic engineering procedures require special regulation. Careful laboratory testing techniques should be followed for all scientific processes. Commercial products demand regulation because of their potential effects on society through widespread use in commerce, not because of their method of production.

The structure which USDA is currently developing already addresses the concerns of H.R. 4452. In November 1985, the Committee on Biotechnology in Agriculture was established to address policy issues throughout USDA and to serve as liaison to other federal agencies concerned with the development of biotechnology. The Department of Agriculture is also developing an advisory committee to review specific research projects in biotechnology. This committee, called the Agricultural Biotechnology Research Advisory Committee, will be composed of individuals with broad scientific expertise as well as knowledge in ethical and social issues. Support for specific project review will be provided through the National Biological Impact Assessment Program by utilizing the diverse agricultural research network which exists across our country. In this fashion, a system similar to the successful NIH RAC will be utilized. This scheme, coupled with existing regulations for commercial products, should provide an orderly and predictable policy. It is also efficient in that it utilizes existing expertise to address current and developing questions of safety in biotechnology.

We commend you for your interest in a safe system within which to conduct research in biotechnology and to develop a sound biotechnology industry.

Sincerely yours,

C B Browning

C. B. Browning, Chairman
Committee on Biotechnology,
NASULGC

jh

cc: Committee on Biotechnology
Judy Kite
John Fulkerson
Pat Jordan

APPENDIX VI

NRARE

The Conservation Foundation

George K.
c: Tom

June 30, 1986

The Honorable James H. Scheuer
Chairman
Subcommittee on Natural Resources,
  Agriculture Research and Environment
House Committee on Science and Technology
Suite 2321 Rayburn House Office Bldg.
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your letter of June 17th inviting us to comment on H.R. 4452, the "Biotechnology Science Coordination Act of 1986." We appreciate this invitation, for we consider the need for a sensitive, yet effective government program to deal with the potential problems and opportunities offered by biotechnology to be of the highest priority. Unfortunately, however, because of prior commitments, we are unable to prepare the thoughtful comments your letter invites by the 1st of July. We apologize for this inability to respond, and hope you will contact us if you address this issue again in the future.

Yours truly,

Edwin H. Clark, II

Edwin H. Clark, II
Vice-President

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WASHINGTON OFFICE
[illegible] JAMES H. SCHEUER, M.C.

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Affiliated with World Wildlife Fund

APPENDIX VII

American Chemical Society

DEPARTMENT OF GOVERNMENT RELATIONS
AND SCIENCE POLICY

1155 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20036
Phone (202) 872-4477

August 4, 1986

The Honorable James H. Scheuer
Chairman
Subcommittee on Natural Resources,
Agriculture Research and Environment
Committee on Science and Technology
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Scheuer:

To ensure a complete hearing record, the American Chemical Society (ACS) is pleased to submit the enclosed answers to questions you have asked of Dr. Judith A. Hautala. Dr. Hautala presented the official ACS testimony during your hearing of June 5, 1986, on H.R.4452, "The Biotechnology Science Coordination Act of 1986."

Since the ACS received these questions so late (thanks to the impact of Gramm-Rudman on franked mail), we appreciate the extension of time you have given us to respond. If you desire further clarification from the Society on any of these or other issues concerning this legislation, please do not hesitate to contact me.

Sincerely yours,

Kathleen A. Ream

Kathleen A. Ream
Head

Enclosure

cc: Dr. J. A. Hautala

KAR/AF/sdh

ACS Response

Question

1. What definition for the terms "release into the environment" and "containment facility" would ACS endorse?

Answer

The ACS suggests the following definitions for consideration:

1a. The term "release into the environment" should refer to the purposeful introduction or exposure into an open environment.

1b. The term "containment facility" should apply to a facility or structure designed or certified to confine an organism and to prevent release above the level of safety. Therefore, a facility would be classified as a containment facility on a case-by-case basis.

ACS Response

Question

2. In light of the recently released federal policy guidelines for the regulation of biotechnology, does the Society feel that the existing statutes provide sufficient authority for agencies to collect data and to conduct appropriate pre-release review of genetically-engineered organisms? Do the current regulatory policies of the agencies reflect the appropriate balance of risks and benefits relating to environmental releases of genetically-engineered organisms? Does H.R.4452 adequately address the statutory deficiencies and the regulatory problems you perceive? If not, what changes in H.R.4452 would ACS recommend?

Answer

2a. The ACS recommends that the appropriate existing statutes be amended as necessary to allow a consistent permitting procedure to be instituted for the release into the environment of genetically engineered organisms. The Society maintains that existing statutes should remain use-oriented and that the current jurisdictional boundaries among federal agencies should remain in place. The ACS does not believe it is necessary at this time to enact new encompassing legislation for the regulation of biotechnology as a whole.

2b. The Society believes that additional research is needed to evaluate the potential risks associated with individual biotechnology activities and to serve as the basis for regulatory decisions in this area. Areas particularly in need of further research include the development of environmental field test methodologies, the detection of genetically engineered organisms in an ecosystem, and the monitoring of the survivability of genetically engineered organisms. Therefore, the ACS strongly endorses the establishment of a biotechnology research program to create a database to support the development and any necessary regulation of biotechnology.

However, the Society believes that such a research program should be federally funded through existing agency mechanisms, though industry should be encouraged to be an active participant. In the interim, the current Biotechnology Science Coordinating Committee (BSCC) should serve as a forum for agencies to discuss their research needs and current programs in biotechnology, and to avoid duplication of effort.

2c. In commenting on provisions of H.R.4452, the Society wishes to highlight the following recommendations:

- The ACS believes that the currently operating BSCC is able to address adequately the near-term problems and to function as the coordinating mechanism until the various federal agencies have gained experience from implementing their regulatory policies. Therefore, no legislative creation of a new single, comprehensive coordinating body is recommended at this time.

- The ACS favors a more flexible permitting system rather than the proposed three-tier approach of H.R.4452. A permit should be granted on a case-by-case basis for those genetically engineered organisms to be released intentionally into the environment (including those to be used for commercial research and development or otherwise to be used in commerce) as well as for those to be used in noncontained manufacturing operations.

  The Society recommends that a permit not be required for genetically engineered organisms that are to be used solely as intermediates in contained manufacturing processes (provided appropriate containment can be assured). Instead, a notification system similar to the premanufacture notification (PMN) procedure currently in effect for new chemicals should be instituted.

  In the case of the environmental release of organisms used in noncommercial research at research institutions, the ACS proposes the establishment of an institutional permit to be modeled after the licensing process implemented for the use of radioactive materials.

  The ACS believes that a provision should be included in the legislation granting the Administrator of EPA the authority to waive the permitting or notification requirements after making a determination, based on scientific finding, that release of the organisms would not create any unreasonable risk to human health or to the environment.

- The ACS believes that a timeframe should be imposed that requires the Agency to make a decision on granting a permit within a specified period after an application is submitted.

ACS Response

Question

3. How would the ACS' suggested institutional permit differ from and provide greater oversight that the institutional biosafety committees required under the National Institute of Health Guidelines?

Answer

3. The ACS has recommended the establishment of an institutional permit to be granted in the case of environmental release of organisms used in noncommercial research at research institutions. Establishing an institutional permit would eliminate the need for each investigator to interact with EPA separately because the permit would be granted to a research institution as a whole. In applying for a permit, these institutions would need to specify the range of research intended, including the organisms to be released, the nature of the field test, and the appropriate controls. Also, research institutions would be required to establish an internal review committee to approve each specific experiment.

Such a system for granting institutional permits for noncommercial biotechnology research at research institutions could be modeled after the licensing process implemented for the use of radioactive materials. In these cases, an institutional permit is granted, which specifies the isotopes that can be used and at what levels. Also, an internal safety committee must be established to develop a set of rules for the use of these materials at the institution.

According to the ACS proposed institutional permit, the research institution would be required to establish an internal environmental review committee that would approve each specific experiment. This proposed committee would have more than advisory ability. Currently, under the NIH Guidelines, reports are submitted to NIH by the principal investigator; only those academic research institutions who have federal funds are compelled to submit reports, and decisions by the current biosafety committees do not have the force of regulatory decisions.

The internal environmental review committees proposed by ACS would differ in three respects from the current institutional biosafety committees:

- Their decisions would have the force of regulation.
- They would have approval authority over all experiments, regardless of the source of funds.
- Their decisions on each specific experiment would be made in compliance with the regulations of the appropriate federal agency.

ACS Response

Question

4. In the preamble to the federal policy statement, the Biotechnology Science Coordinating Committee has proposed several definitions of genetic constructions which would be regulated by federal agencies. Are these definitions sufficient to include all of the organisms for which it would be desirable to have an elevated level of review by the appropriate federal agency?

Answer

4. The ACS recommends the following definition for organisms for which it would be desirable to have an elevated level of review:

   The term "genetically engineered organism" means a live bacterium, virus, fungus, plant cell, plant tissue, animal cell, or animal tissue, which has been deliberately altered to contain genetic material either derived from more than one taxonomic genus or from pathogenic or ecologically disruptive organisms or organisms whose pathogenicity or ecological impact has not yet been evaluated.

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Appendix VIII

Association of Biotechnology Companies

July 21 1986

Hon. James H. Scheuer
Chairman
Subcommitee on Natural Resources,
Agriculture Research and Environment
U.S. House of Representatives
Suite 2321 Rayburn Office Building
Washington, D.C. 20515

Dear Rep. Scheuer:

On behalf of the 165 members of the Association of Biotechnology Companies, I wish to thank you again for the opportunity to appear before the Subcommittees on Natural Resources, Agriculture Research, and Environment and Science, Research and Technology. ABC's members are keenly interested in federal regulation of biotechnology. No other group in the United States is more directly affected by biotechnology regulation than ABC's members. Thus, we always welcome the chance to express ABC's views on this subject to Congress.

In your letter of July 3, 1986, you asked ABC to address certain questions raised by the publication of the new coordinated framework for regulating biotechnology. 51 Fed. Reg. 23,302 (June 26, 1986). The first question is whether the existing statutes provide sufficient authority to the federal agencies.

ABC believes that the existing statutes, as supplemented by the new regulations and regulations adopted earlier, provide the federal agencies with adequate powers to collect data and conduct pre-release review of new genetically engineered organisms. For example, sections 4, 8, 10 and 11 of the Toxic Substances Control Act (TSCA) provide the Environmental Protection Agency with extremely broad authority to collect data. Through its premarket notification provisions (section 5), TSCA also enables EPA to review chemical substances before they are released. Thus, on its face TSCA gives EPA adequate authority to review most proposed environmental releases, as well as to gather substantial information regarding these releases.

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The new regulations, however, enhance EPA's capacity to oversee environmental releases. Section 5(h)(3) of TSCA exempts chemical substances manufactured in small quantities for research and development from the PMN and significant new use requirements. In the new regulations, EPA has announced that this exemption will not be applicable to new microorganisms. EPA intends to require researchers who develop new organisms for commercial purposes to notify EPA prior to release, **regardless** of the quantity of microorganism involved in the R & D testing. 51 Fed. Reg. 23,330.

Similarly, EPA has ample authority over pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Through the experimental use permit system (EUP), EPA will have a full opportunity to review data prior to release of new miccroorganisms. This is true even for small-scale releases. EPA's regulations generally presume that small-scale field testing of pesticides will not require an EUP. In 1984, however, the agency issued an interim policy that removed this presumption for genetically altered pesticides. 49 Fed. Reg. 40,659. The new policy statement retains and refines the requirement for EPA approval prior to field testing of genetically engineered pesticides. 51 Fed. Reg. 23,320-21.

ABC also believes that the United States Department of Agriculture (USDA) possesses sufficient statutory authority to undertake the responsibilities which it is assigned under the coordinated framework. The USDA's array of statutory tools, such as the Federal Plant Pest Act, Federal Noxious Weed Act, and the Plant Quarantine Act, has been tightened by USDA's proposed new regulations regarding plant pests. The proposed regulations establish a permit system for genetically engineered organisms which are plant pests -- or for which there is reason to believe that they may be plant pests. 51 Fed. Reg. 23,352-93. The new regulations will give USDA substantially stronger authority to conduct pre-release reviews.

Moreover, the current regulatory policies of the agencies appear to balance appropriately the risks and benefits of environmental releases. For example, EPA has established -- as ABC suggested in commenting on the December 31, 1984 proposal -- a two-tier system for reviewing EUPs. The amount of data that will be required will largely be a function of the likely degree of risk associated with the release. Id. 23,321-22.

EPA's treatment of noncommercial R & D similarly incorporates a reasonably balanced approach. Under section 5(g) of TSCA, noncommercial R & D is exempt from the PMN and significant new use rule requirements. This exemption is extremely important to the future of the biotechnology industry. The strength of the U.S. biotechnology industry has been basic research, most of which has been conducted at colleges and universities. If these institutions were subject to the full PMN requirement for all environmental releases, research would be channeled to other areas facing less burdensome regulation. Nevertheless, even without a PMN requirement much of the research activity will still be subject to scrutiny by the Occupational Safety and Health Administration, the National Institutes of Health or USDA. Id. 23,331.

Whether the agencies will succeed in practice in adequately balancing risks and benefits remains to be seen, of course. Nonetheless, the current regulatory scheme on its face will enable EPA and USDA to engage in appropriate risk/benefit calculations.

Because ABC does not currently perceive any statutory deficiencies or regulatory problems, ABC does not believe that H.R. 4452 is necessary at this time. As we stated in our earlier testimony, biotechnology is a rapidly evolving industry; any regulatory scheme must possess comparable fluidity. Thus, ABC does not support the enactment of new legislation aimed specifically at environmental release of new microorganisms. Nevertheless, ABC is prepared to work with the Subcommittees in drafting legislation that would appropriately balance risks and benefits, while preserving the regulatory flexibility that is necessary for the successful growth of the U.S. biotechnology industry.

We hope that this supplemental information has been of assistance to you. Should you have any additional questions, or wish ABC's assistance in any matter relating to the biotechnology industry, please do not hesitate to contact us.

Sincerely,

Jeffrey N. Gibbs

Jeffrey N. Gibbs
Associate General Counsel

APPENDIX IX

July 17, 1986

The Honorable James H. Scheuer
Chairman
Subcommittee on Natural Resources
House Committee on Science and Technology
388 HOB Annex #2
Washington, D.C. 20515

Dear Mr. Scheuer:

IBA is responding to written questions directed to us, by your letter of July 3, 1986, regarding the recently released biotechnology regulatory guidelines and how they relate to H.R. 4452.

> 1. In light of the recently released federal policy guidelines for the regulation of biotechnology, does the IBA feel that the existing statutes provide sufficient authority for agencies to collect data and to conduct appropriate pre-release review of genetically-engineered organisms?

It is clear from Chart I in the Administration's proposal (51 FR 23304) that jurisdictional boundaries for product reviews are clearly established. The two agencies responsible for reviewing environmental uses of genetically engineered organisms will be EPA and USDA. In terms of statutory authority and appropriateness the following points are clear:

a) FIFRA provides EPA with ample authority to conduct reviews prior to the release of genetically engineered microbial pesticides to the environment. EPA has already used this authority in the review of several genetically engineered microbial pesticides and has required further data in some instances.

b) Microorganisms and their DNA molecules are "chemical substances" under section 3 of TSCA, and thus are subject to all the provisions of that law. EPA is therefore authorized to use TSCA to regulate certain genetically engineered microbial products that will be used in the environment (the prime example would be in the area of pollution control). Furthermore, the agency is proposing to amend the regulation exempting from PMN requirements research and development for this class of products so as to The Honorable

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specify that field testing of microorganisms does not fall within the definition of "small quantities" for R&D. This will allow EPA to review this class of products prior to field release. IBA believes that this is prudent policy at this point in time because of scientific uncertainties surrounding the use of such products in the environment. We believe that the agency has authority under Section 5 of TSCA to require sufficient data to permit a reasoned assessment of risk prior to environmental use.

c) USDA has sufficient authority under the Virus-Serum-Toxin Act to oversee the field testing of genetically engineered vaccines. USDA is planning to use the Plant Pest Act and the Plant Quarantine Act to regulate the development of genetically engineered crop plants. This is appropriate since the chief concern regarding the introduction into the environment of this class of products would be the creation of a new plant pest. To IBA's knowledge, all of the vectors that are being used for plant genetic engineering purposes are derived from plant pests as outlined at 51 FR 23362. Under USDA's proposal such plants would be reviewed by APHIS prior to release to the environment. If the plant were determined not to be a pest, it could be released into the environment without a license.

2. Do the current regulatory policies of the agencies reflect the appropriate balance of risks and benefits relating to environmental releases of genetically-engineered organisms?

Since the proposed regulations give the agencies oversight of research and development activities at the field testing stage, there is sufficient authority to assess risk and prevent those products that are deemed to pose environmental risk from being released into the field. Benefits to society accrue when a product reaches the commercial stage after a thorough regulatory review.

3. Does H.R. 4452 adequately address the statutory deficiencies and regulatory problems you perceive? If not, what changes in H.R. 4452 would IBA recommend?

IBA believes that there is adequate statutory authority for agencies to review biotechnology products destined for use in the environment and that the Administration's regulatory framework is consistent with statutory authority. Both EPA and USDA have already reviewed such products and it appears as that the process is working well. Unless a specific problem with this present regulatory process can be identified, legislation such as that outlined in H.R. 4452 should not be contemplated.

We hope that these comments are useful to the subcommittees.

Very truly yours,

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